Designing a Wearable Hemodialysis System: a Human Factors Engineering Approach

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Abstract

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End-stage renal disease (ESRD) is a medical condition of permanent kidney failure requiring a patient to either receive a kidney transplant or adhere to long-term dialysis treatments. Dialysis is a life-sustaining method of cleaning and filtering a patient's blood using a dialysis device. The majority of ESRD patients receive hemodialysis treatments where the patient's blood is cleaned and filtered outside of the patient's body using a hemodialysis system. Current hemodialysis systems have not been significantly updated since first pioneered in 1943. Patients still carry a high symptom burden with loss of mobility and independent living while undergoing treatment. However, recent technological advances in hemodialysis treatments allow for the development of a new generation of wearable hemodialysis systems bringing hope to improve ESRD patients' quality of life. Despite the potential to transform the lives of dialysis patients, many obstacles have impeded the development and use of a wearable hemodialysis system. One major hindrance to its development is the lack of adopting a human factors engineering design process that incorporates users' perspectives throughout the entire design process. To this day, no studies exist that gather and characterize the perspectives of distinct user groups at the beginning of the design cycle for a wearable dialysis system. This dissertation aims to fill that gap.

The overall goal of this dissertation is to identify users' perspectives of a wearable hemodialysis system. In particular, by gathering responses from distinct user groups and

employing both qualitative and quantitative methods, this dissertation aims to answer four research questions: (R1) what are patients' and care partners' needs and perspectives of a wearable hemodialysis system? (R2) What are patients' and care partners' needs and expectations for monitoring and training procedures for a wearable hemodialysis system? (R3) What are clinicians' perspectives on a wearable hemodialysis device? and (R4) What is the relationship among user characteristics, human factors design principles, and proposed design concepts of a wearable hemodialysis device?

The results from research questions R1-R3 aim to help developers of a wearable hemodialysis system set design and usability goals to help ensure an optimal design process with a resulting system that meets and supports users' needs. Additionally, the results from research question R4 aim to help developers better understand the relationship among users' demographic characteristics, human factors design principles for wearable medical devices, and designs of a wearable hemodialysis device. Understanding this relationship may help identify important factors that contribute to users' adoption behaviors. As a result, researchers and designers may refine their objectives to help ensure a wearable hemodialysis system that is designed in accordance with users' needs.

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Chapter 1

INTRODUCTION

1.1 End-stage Renal Disease

End-stage renal disease (ESRD) is a medical condition of permanent kidney failure. Although kidney failure can be attributed to blunt kidney injury [216] or trauma causing kidney function impairment [79], kidney failure is most often the result of progressively worsening kidney functioning. The decline in kidney functioning can be attributed to diverse biological reasons where diabetes and hypertension are the two major contributing health conditions [204]. An ESRD patient is an individual suffering from kidney failure. The ideal treatment is to replace an ESRD patient's failed kidney with a functioning one [2]. However, the number of ESRD patients in the United States who have benefited from a functioning kidney transplant comprises only 30% of the ESRD population of the past decade [203]. When the kidneys are no longer able to function normally, waste products and excess fluids build up in the body which can lead to a uremic syndrome that negatively affects multiple organs [84].

Patients who do not receive kidney transplants undergo dialysis treatments to sustain their lives. Dialysis allows an ESRD patient to extend their survival by using a machine that filters salt, waste, and fluids from the patient's blood when their kidneys are no longer able to function normally. At present, over 2 million people receive dialysis treatments in the world; however, the number is expected to double over the next decade largely due to increasing life expectancy and prevalence of hypertension and diabetes [123]. In the United States, the majority of ESRD patients receive hemodialysis treatments, in which a patient's blood is filtered outside the patient's body using a hemodialysis machine. The hemodialysis machine removes, cleans, and returns the patient's blood to their body [85]. At the end of 2019, a total of 566,614 U.S. individuals were receiving dialysis treatments. Of this population, 87% were receiving in-center hemodialysis treatments, 11% were receiving peritoneal dialysis

treatments, in which a patient's blood is filtered inside their abdomen, and 2% were receiving home-based hemodialysis treatments [203].

Hemodialysis treatments and devices have remained largely unchanged since first developed in 1943 by Willem Kolff in Kampen, Netherlands [113, 49], and first commercially started in 1962 by Belding Scribner and colleagues at the University of Washington, WA, USA [19, 20, 88]. The standard in-center hemodialysis treatment schedule requires a patient to travel to a dialysis center and spend multiple hours several times per week connected to a stationary device [85, 78]. Despite being the dominant mode of treatment, in-center hemodialysis has been found to negatively impact patients' quality of life affecting their physical, mental, and social well-being [88, 197]. In the 1960s, researchers began to envision a mobile hemodialysis device resembling an artificial kidney that imitates healthy kidney functioning and overcomes the limitations of current hemodialysis treatments. Despite recent advances that have yielded more efficient dialysis methods, all of which also have the potential to increase patients' mobility during treatment [74, 86, 40], to date, there are no hemodialysis devices on the market that provide an ESRD patient with mobile and continuous hemodialysis treatments [86]. The translation to a mobile hemodialysis device is further complicated by the fact that there are multiple types of vascular access, the method of accessing a patient's bloodstream, each with its strengths and limitations [54, 231]. To date, there is no safe, reliable, and user-friendly vascular connection option that can be used by non-experts to gain vascular access. The major bottlenecks that have hindered the development of a mobile hemodialysis system are largely due to a lack of true user-centered technological innovations that help ensure the system is welcomed by and meets the needs of diverse user groups [86].

1.2 Human Factors Engineering

Human factors engineering (HFE) is a discipline that focuses on optimizing the interaction between humans and systems. In the process of optimizing the human-system interaction, HFE aims to make systems successful by enhancing users' safety, performance, and sat-

isfaction [219]. Although greater importance may sometimes be placed on enhancing one goal over another, for example enhancing safety in high-risk operations [136] or enhancing satisfaction in consumer behavior [77], HFE process protocols can help ensure simultaneous goal achievements [193].

The goals of HFE can be accomplished through the human-centered design cycle. Figure 1.1 shows the cycles of the HFE design process with three major phases: understanding users' needs, creating a system prototype, followed by evaluating the prototype. As the three phases are linked to each other, they form an iterative design cycle where at each step users' perspectives are incorporated and evaluated throughout the design process [219].

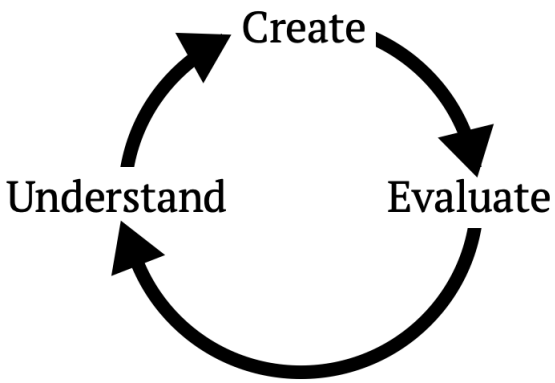

Figure 1.1: Human factors design cycle [219].

The application of HFE in medical device design has garnered increasing attention in terms of the ability to reduce the risk of use error, improve safety, and enhance user experience [18, 214, 179, 80]. Use errors of medical devices can occur in various environments, at various steps in the use process, can occur by any user of the device, and can result in various outcomes including wasted resources, injuries, or deaths [179, 189, 10, 131, 47]. To ensure optimal outcomes, HFE emphasizes early and iterative involvement of intended users in the design process of new medical devices [214]. Studies show that design processes that consider users' needs and preferences from the beginning of the design cycle are most successful and produce longer-lasting products [185]. On the other hand, failing to consider

the needs of diverse users throughout a product design process can impact the potential of achieving optimum clinical and user outcomes [25].

1.3 The Wearable Hemodialysis System

The Center for Dialysis Innovation (CDI) at the University of Washington (UW) is currently heading towards novel technologies and designs for a mobile and wearable dialysis system [108]. The wearable hemodialysis system is comprised of two main devices: 1) the Ambulatory Kidney to Improve Vitality (AKTIV), a wearable hemodialysis device that an ESRD patient can wear on their person while the device performs a dialysis treatment on the patient, and 2) the AKTIV Connection, a standalone vascular connection device intended to connect the AKTIV device to the patient's bloodstream. Figure 1.2 shows the concept construct of the AKTIV wearable hemodialysis system.

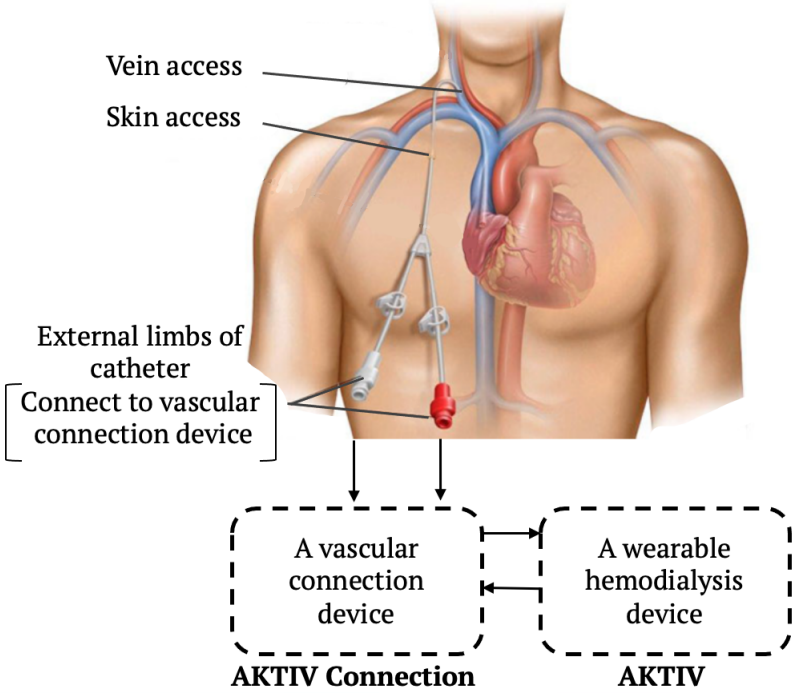

Figure 1.2: A concept construct of the AKTIV wearable hemodialysis system.

The AKTIV is an external, miniaturized, and wearable hemodialysis device that will function to provide renal replacement therapy for patients with end-stage renal disease (ESRD). A wearable hemodialysis device has the potential to offer several benefits to the patients thereby improving the patients' quality of life. For example, offering the patient greater mobility, increases their productivity, social interactions, and employment potential [39]. Additionally, a wearable dialysis device may offer the patient greater control over their treatment schedules which allows the patient to perform longer and or more frequent dialysis treatments which have been found to improve patients' health outcomes [21, 110, 95].

The AKTIV Connection will serve as an adapter to central venous catheters, the only current mode of vascular access for hemodialysis treatments that does not require frequent needle insertions. The AKTIV Connection intends to automate the workflow required to connect and disconnect a patient to and from a hemodialysis device, which is currently done by either trained professionals, care partners, or patients themselves. The goal of automating this workflow is twofold. First, to make the connection and disconnection to the hemodialysis device a user-friendly process by allowing users to safely, easily, and frequently connect and disconnect a patient's bloodstream to a wearable hemodialysis device without the use of needles. Secondly, to reduce the risk of catheter-related infection by minimizing opportunities for touch contamination caused by manual connection and disconnection. No comparable vascular connection device is currently available on the market for ESRD patients.

1.4 Research Objectives

Driven by the overall goal of improving the lives of ESRD patients, this research aims to understand and characterize users' needs and perspectives of a wearable hemodialysis system using a human factors engineering approach. For a wearable hemodialysis system to be successful, it is important to gather users' perspectives at the early stages of the device development process. At this time, users' perspectives are integral to informing the design process, mitigating user risk, and helping ensure end products that meet users' needs [219, 142].

To understand and characterize users' needs and perspectives of a wearable hemodialysis system this dissertation aims to answer the following four research questions:

R1: What are patients' and care partners' needs and perspectives of a wearable hemodialysis system design?

R2: What are patients' and care partners' needs for monitoring and instructional procedures for a wearable hemodialysis system?

R3: What are neprhologists' and nephrology nurses' perspectives on a wearable hemodialysis device design?

R4: What is the relationship between users' characteristics, human factors design principles, and proposed design concepts of a wearable hemodialysis device?

The following sections describe the objectives of each of the four research questions.

1.4.1 R1) What are Patients' and Care Partners' Needs and Perspectives of a Wearable Hemodialysis System?

To answer this question I first characterize patients' unmet need for a wearable hemodialysis system by exploring the challenges patients and care partners face with current hemodialysis systems. Identification of the challenges that patients currently face helps set design justifications according to patients' unmet needs. Secondly, I characterize the intended use environments of a wearable hemodialysis system along with potential use scenarios. Characterizing patients' needs, use environments, and use scenarios helps inform usability objectives that are tailored according to the use intentions. Lastly, I characterize patients' and care partners' perspectives on the early designs of a wearable hemodialysis system that comprises a wearable hemodialysis device, and a vascular connection device. For both devices, I characterize patients' and care partners' perspectives of the primary design forms of the devices, ideal features of the devices, and potential challenges of each device. By characterizing the

initial concept designs of the devices according to users' perspectives, designers and developers can obtain a better understanding of users' needs and set design goals that reflect best human factor practices in meeting users' expectations.

1.4.2 R2) What are Patients' and Care Partners' Needs and Expectations for Monitoring and Training Procedures for a Wearable Hemodialysis System?

To answer this question I first characterize patients' and care partners' design requirements for a monitoring system that supports patients' self-management and symptom-monitoring behaviors. Specifically, I explore patients' and care partners' awareness of ESRD symptoms before and after the patient receives dialysis treatment. Then, I characterize patients' and care partners' design expectations of features of a wearable hemodialysis monitoring system. Lastly, I characterize patients' and care partners' expectations for training procedures before using a wearable hemodialysis system. Characterizing users' needs and expectations for training and monitoring procedures for wearable hemodialysis treatments can help guide design decisions and implementation strategies that support and maintain patients' successful wearable hemodialysis experiences.

1.4.3 R3) What are Clinicians' Perspectives on a Wearable Hemodialysis Device?

Complimentary to exploring patients' and care partners' needs and perspectives of a wearable hemodialysis system, I also characterize nephrologists' and nephrology nurses' perspectives of a wearable hemodialysis device. First, I explore the clinicians' perspectives towards different dialysis modalities and patients' choice of treatment. Then, I characterize clinicians' views on potential benefits for patients afforded by a wearable hemodialysis device. I also characterize potential barriers that may exist hindering clinicians from recommending such a device to their patients. Lastly, I characterize nephrologists' and nephrology nurses' perspectives of the ideal features of a wearable hemodialysis device along with their most preferred design type among five proposed designs of a wearable hemodialysis device. Characterizing clinician's viewpoints brings additional perspectives and helps identify design and implementation aspects unique to clinicians' professional standpoints.

1.4.4 R4) What is the Relationship among User Characteristics, Human Factors Design Principles, and Proposed Design Concepts of a Wearable Hemodialysis Device?

To answer this question propose a structural equation model that examines the relationship among user characteristics, prominent human factors design principles, and five proposed design types of a wearable hemodialysis device. Specifically, I explore the relationship between the users' age, users' gender, and user role; as either a patient, care partner, nephrologist, or nephrology nurse, seven prominent human factors design principles; ease of use, ease of connection, safety, accuracy, comfort, compactness, and invisibility, and five proposed design types of a wearable hemodialysis device; a belt design, a backpack design, a vest design, a shoulder bag design, and a distributed design.

Such exploration has the potential to offer meaningful information both practically and theoretically. From the practical point of view, the results may help identify important demographic traits and design principles that influence users' design type preferences. As a result, designers of a wearable hemodialysis system can refine their design strategies to better meet the needs of users. Theoretically, the results can contribute to the field of structural equation modeling by demonstrating how the technique may be used to investigate complex relationships among users' preference factors. Identifying influencing factors related to the designs of a wearable hemodialysis system, may help guide future research and developments of other life-sustaining wearable medical systems.

The work of this dissertation is structured as follows: section 2 presents the background concerning each of the four research questions. section 3 describes the methodology used in this research, describing the data collection procedures, analysis methods, and the study population. sections 4, 5, 6, and 7, present findings from each of the four research questions in respective order. Lastly, section 8 summarizes the objective of this dissertation and overall results, and discusses potential contributions, limitations, and future research directions.

Chapter 2

BACKGROUND

2.1 Users' Needs and Perspectives of Mobile Medical Devices

In the process of designing and implementing new medical device technologies understanding intended users, their abilities, and needs, from the early design stages of developing new medical devices facilitates an optimal design process and successful medical devices [185, 119, 184, 62, 104].

Shah et al. defined the term 'medical device user' as *'a person who uses a medical device for the treatment and/or care of him- /her-self or someone else'*. They also defined the term 'end-user' as *'a person who is the ultimate beneficiary of the usage of a medical device and who can also be the user of a medical device if using the medical device for him- /her-self.'* Shah and colleagues also classified medical device users into two broad groups: primary users; including healthcare professionals, patients, care partners, and people with special needs, and secondary users; including researchers and others. Trainees and students can be included in either of the two broad groups [184]. Bitkina et al. conducted a multilateral analytical literature review of user experience and usability studies and found that there are four target user groups in medical device design; patients, care partners, health care professionals, and other general users [18].

Following the literature and suggestions from CDI, this dissertation considers four potential user groups of a wearable hemodialysis device; ESRD patients, dialysis care partners, nephrologists, and nephrology nurses. A dialysis care partner is an individual who provides support to a patient with ESRD. The individual is often either a close friend or a family member of an ESRD patient who voluntarily assists the patient in attending their dialysis therapies, health care needs, and activities of daily living [13]. The individual may be living in the same household as the ESRD patient; the individual may also be living elsewhere and providing medical care to the patient during home visits [28]. Currently, many ESRD re-

quire the support of a care partner to undergo their home-hemodialysis treatments. This can be attributed to many patients experiencing physical and psycho-social difficulties resulting from their disease [58] and experiencing challenges posed by current hemodialysis treatments and devices. The currently prescribed in-center treatment schedules allow for three times weekly treatment sessions which has been found to be insufficient in achieving optimal health benefits [172]. Also, current devices do not consider patients' individual characteristics and abilities and restrict the patients' mobility during treatment [86, 206]. Supporting patients' hemodialysis treatments has been found to be significantly burdensome on a care partner impacting their social, emotional, and physical well-being [128].

Recent studies also emphasize the importance of incorporating clinicians' perspectives during early medical device innovation [191]. Their expertise can help assess the conformity of devices including performance, safety, and design, and highlight problem-based needs from both their clinical and patients' perspectives. Yet, studies show that the perspectives of users of medical devices have often been largely absent during the initial concept and design phases and mainly considered during the testing and trial phases [168].

Along with considering users' perspectives, it is also important to characterize intended use environments. Regulators in the U.S. market for medical devices emphasize that among the major components in determining users safe and effective use of medical devices are the intended use environments [104]. A medical device may be able to function safely and effectively in one environment while conditions of other environments can induce risk or use errors [104]. For wearable medical devices, additional environmental considerations need to be taken as the support environment for the device is either the end-user body or their body and their clothing [64]. Currently, no studies exist that characterize users' needs and perspectives of a wearable hemodialysis system, describing intended use environments, and use scenarios of a wearable hemodialysis system. This dissertation aims to fill that gap.

2.1.1 Wearable Hemodialysis Device

While the importance of incorporating patients' perspectives in medical device design is acknowledged, few studies have explored patients' perspectives on mobile medical devices.

Wachtel and colleagues incorporated patients' and healthcare workers' perspectives of inhaler prototypes to improve user experiences and described factors affecting users' inhaler preferences [211]. Papi and colleagues explored patients' perspectives on the design requirements and mode of use of wearable technology to monitor the knee functional status of patients affected by osteoarthritis. Through thematic analysis of focus group sessions where the patients envisioned their most optimal designs, Papi and colleagues identified categories of benefits the technique could offer the patients and also potential challenges hindering patients' adoption of the technology. They further provided detailed descriptions of ideal design requirements including a device that is small, lightweight, and discreet [161]. Bergmann and McGregor conducted a systematic literature review to explore patients' and clinicians' preferences for non-invasive wearable medical sensor systems [16]. The review identified eleven studies incorporating users' perspectives of wearable devices including wearable technology to support rehabilitation of stroke survivors [148], wearable technologies for heart monitoring [55], and a wearable bionic glove to support patients with spinal cord injuries [164].

Within the dialysis community, few studies have explored users' perspectives of ideal device designs, dialysis procedures, or desired outcomes. Morton and colleagues found that both patients and care partners preferred lengthy, home-based dialysis procedures compared to shorter, in-center treatments [146]. Patients and care partners were also found to be willing to accept a shortened life expectancy on dialysis treatment in exchange for reduced travel restrictions. Urquhart-Secord and colleagues, on the other hand, found slight differences in patients' and care partners' dialysis outcome considerations. Patients more frequently considered their ability to work, dialysis-free time, and the treatments' impact on their families, while care partners were more concerned with patients' energy levels, survival rate, anxiety, depression, and ability to travel [202]. Currently, no studies exist that explore the perspectives of different user groups on the designs of a wearable hemodialysis system. This dissertation aims to fill that gap.

2.1.2 Vascular Connection Device

In 1960, the pioneering work of Quinton, Dillard, and Scribner at the University of Washington in long-term vascular accessing facilitated the use of repeated hemodialysis treatments [165, 85]. This foundational work sparked vascular access innovations resulting in various techniques used to this day. The two types of vascular access that are currently widely used for hemodialysis are arteriovenous fistulas and central venous catheters [54]. A fistula is a connection that is made by joining an artery that carries blood from the heart to a vein that carries blood to the heart. This connection requires a large blood vessel to be inserted with a needle before each hemodialysis treatment. The Kidney Disease Outcomes Quality Initiative suggests that a fistula that is surgically placed should be the first choice of physicians and patients. Fistulas pose the lowest risk of morbidity and mortality; they are also inexpensive, have low rates of complications such as thrombosis and infection, and are generally reliable in promoting blood circulation [30, 54, 107, 125, 132]. However, fistulas are limited in use for home hemodialysis systems because self-cannulations, the act of self-inserting a needle into the vascular system, of fistulas are unpleasant, painful, and traumatizing to patients [212]. Moreover, fistulas' high rates of maturation failure, or the failure to be cannulated by two needles on a routine basis, often require surgical intervention [46, 196, 228]. Such limitations of fistulas are linked to the need for a needleless method of vascular access for mobile hemodialysis devices. The current needleless vascular access alternative is a central venous catheter. A central venous catheter can be used immediately and offers patients the option of using various physical sites for insertion. It also ensures pain-free dialysis [29, 75]. Although catheter-related complications remain—indeed, the infection rates of central venous catheters are reportedly higher than those of other types of vascular access [83, 162]—studies show that catheter-related infections can be kept at low rates when adhered to infection prevention protocols [76].

To date, vascular access remains a weak link in facilitating safe and effective hemodialysis treatments [225, 87]. Also, there is currently no safe, reliable, and needleless vascular connection option that can be used by non-experts to gain vascular access. Although studies have explored patients' and clinicians' preferences on the available vascular access modalities

[60, 163, 231] no studies currently exist that include patients as active agents in designing their most ideal vascular connection device. This dissertation aims to fill that gap.

2.2 Supporting Patients' Self-management of Treatment

Patient's and care partner's commitment to managing and maintaining dialysis treatments outside of dialysis centers requires the assumption of significant responsibility in terms of education and self-management behaviors [183]. In terms of patient's self-management of health, knowledge regarding the physical condition and treatment can impact patients' health-related quality of life [37]. Self-management of health is defined as "patients' positive efforts to oversee and participate in their health care to optimize health, prevent complications, control symptoms, marshal medical resources, and minimize the intrusion of the disease into their preferred lifestyles" (p. 386) [38]. Effective self-management of ESRD patients is crucial for improving patients' health outcomes [37] but is complicated and requires support [159]. Yet, patients report a lack of support in self-managing their disease [205].

Studies exploring the effect of monitoring patients' home hemodialysis treatments show that monitoring can help support patients' self-management and symptom-monitoring behaviors. Monitoring ESRD patients has been shown to facilitate patients' well-being [230] and help maintain patients' confidence in their ability to manage their health [96, 122, 130]. For example, successful dietary monitoring can help prevent poor health outcomes [33, 114, 215], treatment adherence monitoring can be used to support or improve adherence [116], and remote monitoring from the dialysis center of patients' bio-metrics can help facilitate timely prescription changes, thereby improving patients' outcomes [153], and reduce unnecessary hospitalizations, resulting in reduced health care costs [120].

Within the body of ESRD educational research, studies show that ESRD patients place great importance on their training and education [170, 176, 159]. Yet, patients report their home hemodialysis education being inadequate [205, 170] with poorly developed training programs that do not recognize or meet their psychological and emotional needs [28, 32]. A review of existing training procedures for current home hemodialysis devices indicated that all potential home-hemodialysis patients must undergo and pass a competency assessment based on a training curriculum. This training and competency assessment usually takes

place in an intimate setting where the patient is taught how to prepare and access their bloodstream; how to set up, operate, and interact with the machine; and how to perform emergency procedures [140]. This training procedure filters out patients who lack motivation, are non-compliant, have poor technique, or are limited in their learning abilities [140, 223]. Furthermore, patient educational content is often developed and seen from the perspectives of health care professionals, not considering patients' individual needs [192]. This form of training and education is therefore essentially a selection process rather than a process tailored to the needs of diverse users and studies show that current training and educational procedures currently act as barriers to patients' successful home-dialysis experiences [28, 32, 70, 126].

In the context of the literature for home-hemodialysis therapies, there is a lack of research exploring and characterizing users' expectations for training and monitoring procedures. Xi and colleagues found out that a patient-centered education coupled with a supportive monitoring system can help facilitate successful home hemodialysis treatments but did not report or characterize such procedures [226]. Studies have called for innovation in home dialysis education to improve patients' confidence in self-managing their treatments and help promote successful home dialysis therapies [73]. To help ensure users' acceptance of wearable hemodialysis devices, it is important to understand patients' and care partners' design expectations for associated monitoring and instructional procedures. Engaging users and characterizing procedures according to users' individual needs may help break down barriers to patients' successful and independent hemodialysis treatments [221]. To date, that are no studies that characterize patients' and care partners' perspectives of monitoring and training procedures for a wearable hemodialysis system. This dissertation aims to fill that gap.

2.3 Modeling the Relationship Between Users' Role, Human Factors Design Principles, and Designs of a Wearable Hemodialysis Device

Several factors have been reported to affect the reasons behind users' successful adoption of wearable devices. Ferguson et al. (2020) explored clinicians' perspectives on wearable cardiac technology and found that patients' age may present challenges negatively impacting

device adoption [56]. Similarly, Gimhae (2013) identified users' characteristics, including age and gender, as being key factors influencing users' successful adoption of wearable technology [69]. The study found that elderly people often lack the same technological experience as those of a younger age and fear making mistakes while interacting with wearable technology. Regarding gender, Schaar & Ziefle (2011) found men to be more accepting of wearable technology whereas women reported fear related to the ease of using such wearable technologies [180]. Device adoption has also been found to be influenced by clinicians' perspectives. Clinicians' characteristics and assumptions regarding patients' needs have been found to strongly influence the recommendation of medical technology for patients [149, 198].

Multiple human factors design principles for wearable devices have been recommended to incorporate into a design cycle to ensure successful device adoption. Motti and Caine (2014) recommend considering 20 human factors design principles for wearable devices to help improve user acceptance [147]. These principles include ensuring the user's comfort while wearing the device, designing a small and lightweight device, ensuring the ease of using the device and ensuring user privacy. Sethumadhavan (2018) recommends considering four main domains of design principles for wearable devices highlighting users' comfort and privacy [182]. For wearable medical devices, Rodriquez-Villegas et al. (2018) highlight additional design principles for ensuring clinical reliability and efficacy. However, Rodriquez-Villegas et al. point out that deciding which human factors design principles to incorporate into a design process hinges on the wearable medical device type. Considering the broad range of wearable medical devices, from consumer health and wellness products to life-sustaining devices [45, 147], design principles may differ in importance based on user needs. For example, the needs of users who are prescribed long-term use of a life-sustaining device may differ from users who willingly make a purchase, and the disuse of the device does not affect their life expectancy [173].

Structural equation modeling (SEM) is a statistical modeling technique particularly useful to simultaneously examine complex relationships between multiple variables (cite). The overall goal of SEM is to test a theory by specifying a model that represents relationships among variables [82]. The main feature of SEM is the ability to include both observed and unobserved variables. Observed variables are variables that the researcher directly measures

while unobserved variables are latent variables, not included in the dataset, that are derived from common factors of the measured variables [111]. The latent variables in SEM can represent broad hypothetical constructs that are not directly observable by one single measure [22]. An example of such a hypothetical construct includes peoples' subjective beliefs such as the perceived usefulness of a system [41]. Another main advantage of SEM is the ability of the technique to account for unexplained variance. While observed measures are not perfectly reliable and include random errors partially due to measurement errors, which in turn may bias the estimated relationship between observed measures, latent variables separate unexplained variance from the true variance of the observed measures. As a result, the latent variables are free from measurement error and produce better-estimated relationships between variables [111].

Factors contributing to the successful adoption of wearable medical technology using structural equation models (SEM) have been well-studied [44, 227, 106]. Degerli & Yildirim (2022) gathered numerous factors and used SEM to identify eleven critical success factors contributing to users' adoption of wearable medical devices including user characteristics, perceived ease of use, user privacy, and device design [45]. Xinyan et al. (2002) used SEM to explore factors affecting senior adults' intentions to adopt wearable medical devices and identified contributing factors of perceived health improvement expectancy and device reliability [227]. Similarly, Khakurel explored users' acceptance of wearable self-tracking devices and found that users' characteristics, privacy concerns, and device designs are important factors that influence continuous use intention [106].

Although the literature suggests several factors affect users' perspectives of wearable medical devices, no studies have yet been identified that simultaneously examine the relationship among user characteristics, human factors design principles for wearable medical devices, and different designs of wearable hemodialysis devices. Such exploration may be instrumental in enlightening the understanding of users' perspectives that in return help guide design developments of different design prototypes.

Chapter 3

METHODOLOGY

3.1 Data Collection Procedure

This dissertation considers four potential user groups of a wearable dialysis system, patients with ESRD, care partners of patients with ESRD, nephrology nurses, and nephrologists. The study began by recruiting patients and care partners who were jointly recruited in two rounds where each recruitment group will be referred to as the primary and secondary study populations. Then, two additional user groups were recruited, nephrology nurses and nephrologists who will be jointly referred to as clinicians.

All participants were recruited and interviewed in two separate sessions. Two populations of patients and care partners were recruited, which in this proposal will be referred to as the primary and secondary study populations. The primary study population was recruited with the overall goal of gathering patients' and care partners' experiences with dialysis treatments and exploring their perspectives on the best designs for a wearable hemodialysis device. The secondary study was conducted to better understand patients' and care partners' perspectives in terms of mobile hemodialysis treatments and the ideal features of a vascular connection device, that supports the user in safely and effectively connecting and disconnecting the wearable hemodialysis device to a patient's bloodstream. Recognizing the important role of nephrology nurses and nephrologists in early medical device design, this study also recruited two additional user groups, nephrology nurses and nephrologists. The overall goal of recruiting nephrology nurses and nephrologists was to gather their perspectives on wearable hemodialysis treatments and ideal device designs. Detailed descriptions of the collection procedures are found in section 3.1.

3.1.1 Patients and Care Partners: Primary Data Collection Procedure

The primary data collection procedures took place over a four-month period in 2019. The data collection process consisted of five stages (a)-(e) shown in Figure 3.1.

Stage (a) included developing the data collection instruments including a survey and an interview script that were collaboratively made by a research team comprised of human factors engineers at UW and researchers at CDI involved with other research aspects of designing a wearable hemodialysis system. Then, prior to conducting the data collection process, three local study site-affiliated research coordinators, all female, met with the research team to familiarize themselves with the concept of a wearable hemodialysis device, as they had not been previously involved with research on the topic. The three research coordinators also familiarized themselves with the interview script, and protocols, made suggestions for improvements, and established interview consistency among the three sites to avoid potential bias. Study inclusion criteria required the care partners to not provide care for the patients enrolled in this study. Instead, the care partners should be providing care to other patients with kidney disease. The care partners should also not have kidney disease requiring dialysis themselves. This was to avoid the possibility that the patients and their care partners might provide similar responses during the interviews. The decision to recruit patients and care partners individually and not as dyads was guided by the goal of the study; to explore individual expectations rather than shared experiences, and to optimize data diversity with respect to research constraints. Recruiting patients and care partners independently from their partners and not as patient-care partner dyads, allows the participants to tell stories from their perspectives. Such recruitment procedures also avoid potential limiting influence on provided information caused by partners being audiences to each other. As a result, richer information may be obtained which in return increases the trustworthiness of the study [50].

Stage (b-c) of the data collection process, included recruiting participants and administering a survey. The primary study population was recruited from three locations within the Veterans Affairs (VA) Health Care System in the United States: Seattle, WA; Nashville, TN; and Louisville, KY. The recruitment stage included contacting and building a rapport with

the participants. At each of the three VA locations, a local research coordinator approached potential participants while they were either receiving dialysis treatment as a patient or accompanying someone receiving dialysis treatment as a care partner. The research coordinators approached individuals and identified them as potential participants by first asking them if they were at the dialysis center to receive dialysis treatment as a patient or accompanying a patient as a care partner. At this screening step of the recruitment process, the research coordinators ensured that patients and care partners were not recruited as dyads but instead as individuals. In terms of building a rapport with the participants during the recruitment stage, the interviewers familiarized the participants with the concept of a wearable hemodialysis device and described that the goal of the study was to learn from patients and care partners what their preferences concerning designing and developing the device, making it easy for patients to continuously use the device in different settings. At the time of the recruitment, all participants were provided with information explaining the objective of the study and allowed to ask questions before agreeing to participate in the study.

Upon receiving a positive response from a participant, the participant received a survey that included demographic questions and questions regarding participants' knowledge of and history with mobile medical devices (Table 3.1). For exploring participants' familiarity with mobile medical devices a five-point Likert familiarity scale was selected to measure participants' self-reported familiarity levels. The 5-point Likert scale was chosen for its midpoint reliability and validity [158], and for being simplistic while still maintaining validity and reliability for the interval data [35]. The survey also included open-ended questions intended to gather patients' and care partners' unbiased responses regarding their most ideal wearable hemodialysis device designs. Specifically, the participants were asked *"on which part of your (your patient partners') body would you (they) ideally wear the device?"* (section 4.2.1), *"please take a moment to think about your ideal mobile hemodialysis device. Draw or describe the ideal mobile hemodialysis device.* (section 4.2.1), and *" what would be the most important features? Are there any other features you would like to mention?"* (section 4.2.2). Such open-ended questions are consistent with how to frame the choices in qualitative research and leave open any idea of a device type the respondent wants to consider.

Stage (d) of the data collection process included an interview with a participant. Each participant was given a choice of where to conduct the interview: at their home, at their respective VA research location, or at the dialysis clinic where they were recruited (provided privacy could be ensured at the clinic). All patients and care partners chose to be interviewed at their respective dialysis centers. The in-person interview included ranking, rating, and open-ended questions and consisted of two main parts. First, the participants were asked to indicate potential use-case scenarios of a wearable hemodialysis device and reflect on the design types and proposed ideal attributes of a wearable hemodialysis device. In exploring potential use-case scenarios, the participants were asked to think about a wearable hemodialysis device and then asked *"what activities would you (your patient partner) like to do while wearing a hemodialysis device?"* (section 4.1.5). Then, five proposed design concepts of a wearable hemodialysis device were introduced to the participants: a backpack, a belt, a vest, a shoulder bag, and a distributed model (a model in which the various parts of the device are separated from one another on the body). The participants were asked to give preference ratings for each design concept (0 = least, 10 = most) 7.3 and subsequently rank each design in order of preference (1=most, 5=least) (section 4.2.1). Exploring some of the concerns the participants might have in relation to the five proposed designs of a wearable hemodialysis system, the participants were further asked *are there any features associated with the five proposed design concepts that concern you? If so, why?* (section 4.2.3). The participants were also asked to think about the qualities they considered important in a wearable dialysis device and asked to give importance ratings (0 = least, 10 = most) and ranking (1=most, 7=least) for seven selected human factors design principles: accuracy (of the device) ease of use, ease of connection (to the bloodstream), comfort (of the patient while wearing the device), compactness, invisibility, and safety (sections 7.3 and 4.2.2). “Accuracy” refers to how accurately the device functions relative to healthy kidney functions, “ease of connection” refers to how easy it is for a patient to put on the device and attach it to their bloodstream, “comfort” refers to how comfortable the patient feels wearing the device, “safety” refers to how safe the device is in terms of not causing immediate or long-term harm to the patient, “compactness” refers to how small and lightweight the device is, “ease of use” refers to how easy it is to operate the device, and “invisibility” refers to how inconspicuous

the device is. The seven attributes were identified based on prominent human-factors considerations in designing wearable devices—comfort, ease of use, wearability, affordability, and reliability—as well as three usability metrics outlined by the International Organization for Standardization (ISO)—effectiveness, efficiency, and satisfaction [147]. Secondly, the participants were asked to reflect on their current hemodialysis experiences to explore users' need for a wearable hemodialysis device. The participants were asked whether they experienced any challenges with current hemodialysis procedures, particularly any physical or emotional challenges. The participants were asked *"do/did you experience any physical challenges such as positions, mobility, using your current or previous dialysis system? If yes, can you provide me with an example of why it was a physical challenge?"* and *"do/did you experience any mental challenges such as stress, depression, or frustration when using your current or previous dialysis system? If yes, can you provide me with an example of why there were mental challenges?"* (section **??**). The participants were also asked about any physical signs indicating patients' need for dialysis treatment or physical signs indicating the successful removal of excess water, solutes, and toxins from patients' blood. Specifically, the participants were asked: *"how do you know if you (or your patient partner) need(s) to receive dialysis?"* (section 5.1.1) and *"how do you know when dialysis was performed well?"* (section 5.1.2).

Interviews were ended by offering the interviewees an opportunity to share any remaining ideas or concerns that they had about the concept of a wearable dialysis device and compensating the participants for their contribution. Each participant was provided with a cash card as a token of appreciation. Compensating participants in clinical studies has become an established practice. Study compensation may help relieve participants of their financial sacrifices, acknowledge participants' contributions to medical sciences, and accelerate the process of reaching the optimal number of study participants [160]. Completing the two stages, the survey and the interview, took each participant approximately 45 minutes in total.

Stage (e) of the data collection process included data gathering and ensuring an optimal number of participants had been achieved. Upon completion of the interviews, audio recordings and interview forms were reviewed to ensure no patient-identifying information

and high audio quality, before being sent to the online transcription service Verbal-Ink ™. A purposive sampling approach with advanced planning of the number of target participants was used. Even though there are no established criteria for the number of interviewees in qualitative studies [12], the literature suggests that when analyzing in-depth interviews, it is common for researchers to use between 1 and 30 participants [65] and moreover, that data saturation might be achieved with 12 participants [72].

The rationale for conducting the survey and interviews separately and sequentially was twofold. First, the survey was intended to limit the risk of interview fatigue [117]. For this reason, each participant's demographic and background responses were gathered prior to their interview. Second, as there is currently no wearable hemodialysis system on the market, the goal was to encourage participants to begin thinking about and envisioning the concept prior to the interview.

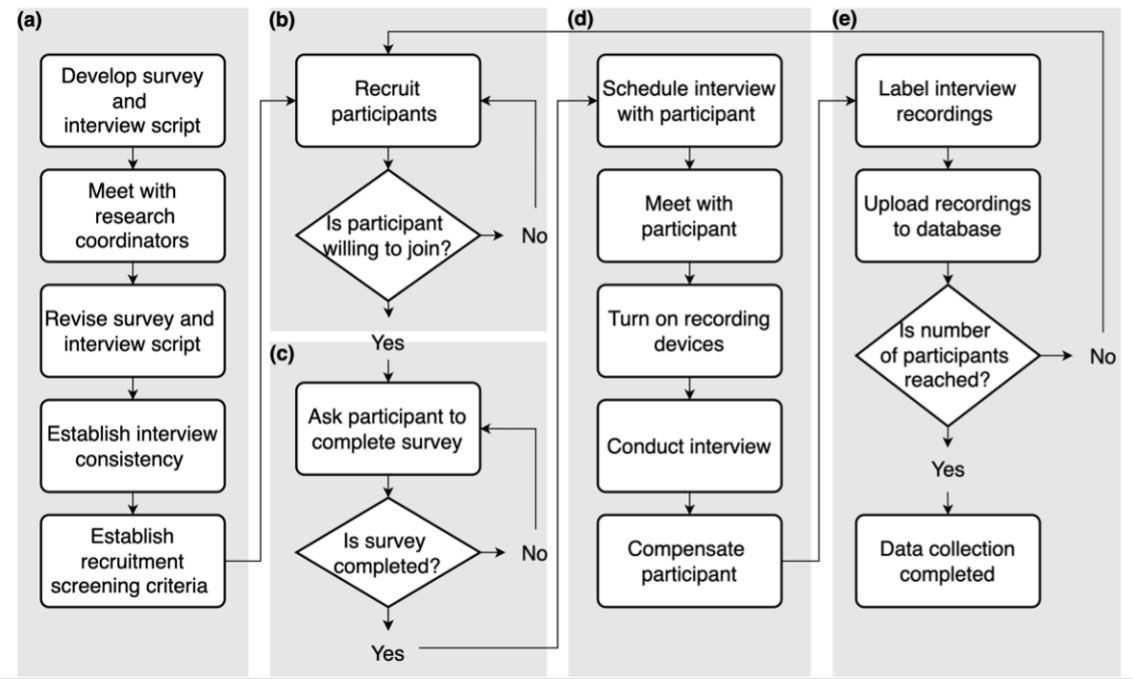

Figure 3.1: Flowchart of the data collection process.

3.1.2 Patients and Care Partners: Secondary Data Collection Procedure

The secondary data collection procedure took place over six months from July to December in 2020. Similar to the primary data collection procedure, the secondary interview procedure followed similar steps as described in section 3.1.1. What follows are descriptions of how the secondary data collection procedure differed from the primary.

Stage (a) of the secondary data collection process considered a single research coordinator across one study site compared to three research coordinators across three study sides in the primary study. The research coordinator is a graduate of the Master of Health Informatics and Health Information Management program at the University of Washington with extensive training and experience in interviewing and data collection. To ensure data collection consistency, the research coordinator gathered all data. This decision was made after observing interview inconsistencies across study sites in the primary study population interview process.

Stage (b-c) of the secondary data collection process included different recruitment procedures. The secondary study population was recruited through the Northwest Kidney Center (NKC) in Seattle, WA, USA. First, potential patients and care partners were identified by the director of external relations and patient engagement at the Kidney Research Institute, a collaboration between Northwest Kidney Centers and the University of Washington Medicine, and the staff at CDI. Then, the research coordinator contacted the patients and care partners by email or phone. The research coordinator described the goal of the study and explained that the study called for two-step participation, survey completion, and partaking in an individual interview with a single interviewer. Upon agreeing to participate, the participant was given a choice of completing a survey either electronically as a digital document sent to the patient's email address to be completed over the internet, or manually as a paper document sent to the patient's physical home address. The paper-based survey would be filled out by the patient and later returned back to the research coordinator during their next visit to their regular dialysis center. The survey gathered participants' demographic and background information related to their dialysis experiences (Tables 3.2 and 3.3, respectively). The survey also included open-ended questions that asked the partici-

pants to state the motivations behind their travels (section 4.1.3) and related travel concerns, if any (section 4.1.4). Specifically, the participants were asked *"What motivates your travels? if anything"*. The participants were then presented with the following ten potential motivations: visiting friends or family, business trips, seeking healthcare services, historic or cultural experiences, sports events (e.g., soccer or football games), outdoor recreation (e.g., surfing, skiing, golfing), scenic or natural attractions, socializing or dating, escape or relaxation, warmer climate, and other (please specify). In terms of related travel concerns, the following question then asked the participants *what are some of your (your as a care partner) concerns in relation to planning an overnight travel (for your patient partner)?*. The survey for the secondary study population did not ask the participants to draw or describe their most ideal vascular connection device. This decision was made after observing the primary study participants experiencing difficulties in drawing or describing their most ideal wearable hemodialysis device. Instead, more targeted questions for ideal form factors and shapes were to be included in the interview.

Stage (d) of the secondary data collection process included a computer-based interview with the research coordinator. First, the research coordinator contacted the participant and scheduled a convenient time slot for the interview. Then the participant was sent a web link to their email address that guided them to the interview platform. The virtual interviews were conducted over the Zoom video conference platform where the participant met with the research coordinator who also conducted the interview. The computer-based interview consisted of two main parts and was in a semi-structured form including both open-ended and multiple-choice questions. In the open-ended questions, the participants were asked to reflect on their personal needs and experiences while the care partners were asked to reflect on the needs and experiences of their care recipients. The first main part of the interview aimed at exploring participants' perspectives of mobile hemodialysis treatments and their willingness to use a mobile hemodialysis device in different environments (section 4.1.2). The second main part aimed at gathering participants' perspectives towards the use and designs of a vascular connection device guiding designers to reach design parameters meeting users' acceptance criteria. Firstly, as the vascular connection device may be designed based on bloodstream access via a catheter, the participants were asked questions about the ideal

physical location of a catheter and concerns regarding connecting a vascular connection device to a catheter. In particular, the participants were asked the following open-ended question: *"thinking about this vascular access device, where do you think would be the ideal part of the body for the catheter line to exit?"* (section 4.3.1). This question was asked to help inform the early design conceptualization of vascular connection device locations so that they would reflect participants' needs and preferences. The participants were also asked whether they had any concerns over self-connecting the catheter lines to a vascular connection device. Specifically. the participants were asked the open-ended questions *"what would be some of your concerns in relation to connecting your (your care recipients') catheter lines to the vascular access device? Are there any other concerns that you can think of?"* and *"would you be concerned about making the connection in public? If yes, can you tell me some of your concerns?"* (sections 4.3.3 and 4.3.3, respectively). These questions aimed to explore potential barriers to patients' and care partners' self-management of vascular connections and patients' and care partners' concerns regarding the freedom of treatment timing and location. Secondly, to determine the acceptable compactness of a vascular connection device, the participants were asked open-ended questions about the upper limits for the size and weight of the device. Since it was expected that some participants would have difficulty answering these questions, the participants were provided with multiple-choice options for the largest acceptable size and heaviest weight of a vascular connection device whenever the participants were unable to open-endedly give estimates of the parameters. The options presented for the largest acceptable size of a vascular connection device were as follows: a backpack (22 x 30 x 42 in), a cross-body bag (10 x 23 x 30 in), a belt bag (8 x 10 x 28 cm), a smartphone (0.8 x 8 x 15 cm), and a credit card (0.5 x 8 x 10 cm). To determine what a participant considered to be the largest acceptable size, the options were presented in the order of largest to smallest, pausing for an acceptable answer after each option was presented. The same familiar objects were used to determine what a participant considered to be the heaviest acceptable weight: a backpack (4.5 kg), a cross-body bag (2.3 kg), a belt bag (0.9 kg), a smartphone (0.23 kg), and a credit card (0.09 kg). The participants were asked, *"what do you think would be the largest acceptable size of a vascular connection device to carry while dialyzing?"* (section 4.3.1). Then the participants were asked, *"still thinking*

about the vascular connection device that you (your care recipient) would be carrying on your body, what do you think would be the heaviest acceptable weight of the device?" (section 4.3.1). Thirdly, the participants were also asked to envision the most ideal designs of a vascular connection device including the ideal shape of the device and ideal features of the device. To explore the shape of a device that the patients would feel comfortable holding, using, and carrying on their person, the participants were asked the following open-ended question: *"what would be the most ideal shape of the vascular connection device?"* (section 4.3.1). To gather insights into the ideal features to be included in the designs of the device, the participants were asked another open-ended question: *"what would be some ideal features that the device would have in relation to connecting to your (or your care recipient) catheter? Are there any other ideal features that you can think of?"* (section 4.3.2). Exploring potential physical locations for wearing or carrying a vascular connection device, the participants were asked to rank in order of preference (1 = not at all interested, 5 = very interested) five potential physical locations: a pocket on the upper torso, waist belt or bag, front pocket on pants, back pocket on pants, and a shoulder bag (section 4.3.1). Lastly, the participants were asked to envision themselves using a vascular connection device to connect their (or their care recipients') bloodstream to a mobile hemodialysis device. The goal of the questions was to gain insight into fundamental use-case scenarios related to the greatest amount of time the participants were willing to spend in making a vascular connection using the device. Specifically, the participants were asked *"what would be the longest time spent you could accept in making the blood connection?"* (section 4.3.4) and *"how many times per day do you think you would be willing to connect and disconnect to the vascular connection device for a mobile hemodialysis treatment?"* (section 4.3.4).

3.1.3 Clinicians: Data Collection Procedure

The clinician's data collection was conducted over a six-month period, from July to December 2021, and consisted of five stages as shown in Figure 3.1.

Stage (a) of the clinician's data collection process included the development of the data collection instruments and considered an additional two research coordinators, the director

of strategic relations and patient engagement of the American Society of Nephrology (ASN) and the executive director of the American Nephrology Nurses Association (ANNA). Each research coordinator also oversaw the recruitment of their respective site.

The data collection instruments included both a survey and an interview script similar to previous data collection procedures. The data collection instruments were developed by UW and CDI researchers and collaboratively revised by the whole research team. The study aimed to recruit a national sample of clinical partners therefore the participants were selected based on representing diverse geographic locations and areas of nephrology expertise. Additional study inclusion criteria required the clinicians to have a minimum of two years of practice experience.

Stages (b-c) of the clinician's data collection process included recruitment of prospective participants and administering a survey.

The nephrologists recruited for this study were all members of the American Society of Nephrology (ASN). With 20,472 global members, ASN is a non-profit, tax-exempt alliance for kidney health. The mission of ASN (2023) is to "elevate care by educating and informing, driving breakthroughs and innovation, and advocating for policies that create transformative changes in kidney medicine throughout the world." Over the last decade, ASN has sought to stimulate innovation in kidney care. Their efforts include encouraging innovators in nephrology to include users early and iteratively throughout their design process. The nurses recruited for this study specialized in nephrology and were all members of the American Nephrology Nurses Association (ANNA). Since its establishment as a nonprofit organization in 1969, ANNA's mission is to improve members' lives through education, advocacy, networking, and science. ANNA has a membership of over 8,000 registered nurses and healthcare professionals who practice in all areas of nephrology.

While the nephrologists were directly contacted via email by ASN's director of strategic relations and patient engagement, an open call for study participation was included in a monthly electronic newsletter sent out to all members of ANNA. The recruitment email and the electronic newsletter asked for volunteers with experience in home dialysis and home therapies to participate in research and inform the technology developments of a wearable hemodialysis device. The recruitment study invitation also described the goal of ensuring

the perspectives of all users are included in the early development of new kidney technology. Upon receiving a positive response from a contacted nephrologist, the nephrologist was sent a link to an electronic survey platform. The electronic newsletter sent to members of ANNA included the hyperlink directing interested members directly to the electronic survey platform.

Recruitment procedures continued until an ideal number of participants had been reached. An ideal number of participants was determined following three criteria. First, following previous studies, it was determined that between 12 and 30 participants would be sufficient for achieving data saturation for qualitative analysis of open-ended questions [36, 72]. Second, an a priori analysis indicated that 24 participants would yield 80% power with a medium effect size ($\eta^2 = 0.6$, f = 0.25) for detecting statistically significant differences in the quantitative analysis of the rank-ordered questions [52, 207]. Lastly, to account for the potential effects of attrition or incomplete participation, and to avoid a potential limiting effect in our quantitative analysis, additional participants were recruited. Ultimately, 30 nephrologists and 32 nephrology nurses individuals were chosen to partake in this study.

The electronic survey was designed to gather participants' demographic information, number of years in dialysis practice, and experience with different modes of dialysis therapies, including the average number of patients they were currently treating under each mode of therapy 3.4. The clinicians were also asked to rate on a scale from 1 (strongly disagree) to 5 (strongly agree) statements regarding dialysis therapies and programs, treatment modifications, and prescriptions. They were also asked to respond to statements regarding the potential of improving patients' quality of life using a wearable hemodialysis device (sections: 6.1.1 and 6.2.1). The survey questions were intended to align with the goal of the study of exploring clinician's perspectives of hemodialysis treatments and were developed based on previous a study exploring clinicians' attitudes toward dialysis treatments and modifications [61]. Upon completion of the electronic survey, each participant was given a unique study identification number and guided to an online scheduling platform where the participants selected a convenient date and time for an interview.

Stage (d) of the data collection process included a one-on-one interview. The interviews took place over Zoom, a video conferencing platform, where the participants were given

the choice of attending the interview with or without transmitting a video of themselves. The interviews were conducted by an industrial engineer with experience in conducting interviews for human factors engineering studies [99, 98, 97]. The interviewer followed an interview guide that had been developed by the research team and subsequently reviewed by the leaders of ASN and ANNA to ensure the interview script was in line with the invitation to participate. ASN and ANNA staff did not participate in the interviews or review any results before the development of this study.

The goal of the interview was to gather nephrology nurses' and nephrologists' perspectives on a wearable hemodialysis device and included both open-ended, rating, and rank-order questions. During the virtual interviews, the participants were asked an open-ended question gathering their thoughts on the benefits a wearable hemodialysis device could offer an ESRD patient. More specifically, the participants were asked the open-ended question *"think of a patient having their own wearable hemodialysis device. What are some of the benefits (i.e., advantages) you see for a patient in having their own wearable hemodialysis device? Are there any other benefits that you can think of?"* (sections 6.1.2 and 6.2.2). Then, the participants were asked an open-ended question gathering potential barriers that would prevent them from recommending a wearable hemodialysis device to their patients. More specifically, the participants were asked *"what would be some of the barriers preventing you in recommending the use of a wearable dialysis device to your patients (while operating the device and the long-term use)?"* (sections 6.1.3 and 6.2.3), and open-endedly asked to name ideal features to be included in the design of the device to ensure the participants would feel comfortable recommending the device to their patients. More specifically, the participants were asked *"still thinking about a wearable hemodialysis device, what features, or characteristics must the device hold for you to feel confident in recommending it for patients?"* (sections 6.1.4 and 6.2.4). Lastly, the participants were asked to think about designing a wearable hemodialysis device and give importance ratings (0 = least, 10 = most) for seven selected human factors design principles: accuracy (of the device) ease of use, ease of connection (to the bloodstream), comfort (of the patient while wearing the device), compactness, invisibility, and safety 7.3. Subsequently, the participants were asked to give importance ratings (0 = least, 10 = most) and rankings (1=most, 5=least) for five proposed

design concepts of a wearable hemodialysis device: a backpack design, a belt design, a vest design, a shoulder bag design, and a distributed design - a design where components of the device may be worn on different physical locations (sections 7.3), 6.1.5, and 6.2.5).

section (e) included labeling the recorded interview file with participant's identification numbers to ensure anonymity. Then the recording was sent to GMRTranscription, an online transcription service, where the file was transcribed verbatim. Upon study completion, each participant was sent a $100 prepaid debit card as a token of appreciation for their efforts in contributing to the research. The average duration of completing the electronic survey was 10 minutes and 45 minutes for the virtual interview. The study was qualified as exempt, posing no or minimal risk to participants, by the University of Washington Internal Review Board.

3.2 Analysis

A mixed-method approach of qualitative analysis of the open-ended questions and quantitative analysis of rating and rank-order questions was used to analyze survey and interview responses.

3.2.1 Qualitative Analysis

All open-ended questions (see sections 4.1.1, 4.1.2, 4.2.1, 4.2.2, 4.2.3, 4.3.1, 4.3.2, 4.3.3, 4.3.4, 5.1, 5.2, 5.3, 6.1.2, 6.1.3, 6.1.4, 6.1.5, 6.2.2, 6.2.3, 6.2.4, 6.2.5), were analyzed using a content analysis approach [51, 92, 144], which is a qualitative research technique that is particularly useful for analyzing textual data with limited structure. By using this technique, researchers can identify themes or categories from direct information from the participants rather than imposing predetermined categories or attributes on the participants [92].

Inductive Content Analysis

For the inductive content analysis, all the transcribed interviews were carefully read by the author of this proposal to gain knowledge of the interview data before starting the analysis process. This was an important step in achieving immersion of the data before the coding

process begins [138, 144, 145, 195]. For the inductive content analysis, structural coding was conducted using the software ATLAS.ti [150]. In this stage, large segments of participants' full responses to the questions of interest were captured to preserve the context of the interview data. Then, each segment was analyzed. Keywords and short phrases uttered by the participants were highlighted and coded using either the direct words as keywords or the direct short phrases as quotations and marked by participants' study identification (ID) number. This was purposefully done to preserve the context of the data. A word was identified as a keyword if it was in the form of an attribute related to the question of interest. For example, the participants were asked, *how do you know if dialysis was performed well?"* One participant responded, *"my weight goes down and I have more energy."* This response had two keywords, "weight" and "energy," which were coded "weight goes down" and "more energy" to preserve the context of the keyword. The former was later rephrased to "weight loss" to be documented with another participant's comment. The keywords and quotations were exported from the coding software to a spreadsheet to form an initial code book. At this stage of the analysis, a second coder who advises the author joined in analyzing the interviews by confirming that all keywords and comments had been correctly captured and identified. In the event of discrepancies, adjustments were collaboratively made. Lastly, the codes were organized into categories based on code commonalities. Code commonalities were identified when keywords or phrases were related to the same attribute. An overarching concept was chosen to describe each category where the repetition of keywords was the strategy most frequently used to identify a theme and to form and name each category [178]. However, during the analysis process, it was noticed that by focusing only on repetitions, certain important comments made by the participants might have been overlooked. For this reason, a decision was made to include all responses that included a keyword in the form of an attribute of interest, no matter how often it was mentioned.

Deductive Content Analysis

One finding (section 5.2) was obtained using a deductive content analysis approach [51]. This was done to extend the understanding of patients' and care partners' monitoring ex-

pectations as monitoring had previously been identified as an important feature of a mobile hemodialysis device [97]. For the deductive content analysis, a more directed analysis approach was used where attributes related to participants' expectations of monitoring procedures for mobile hemodialysis treatments were systematically identified. This was done to extend the understanding of patients' and care partners' needs for monitoring features as monitoring had previously been identified as an important feature of a dialysis device [97]. The deductive content analysis strategy was performed in three stages. First, the transcribed interviews were carefully read by the author of this proposal and structural coding was conducted. Instances related to monitoring were highlighted and coded using the temporary code "monitoring." Then, the highlighted and coded sections were exported to a spreadsheet where a dual coding process was initiated. Keywords related to monitoring were extracted from each coded section and sorted into categories. Then, a second round of coding was conducted. All transcripts were searched using keywords related to monitoring; namely, "monitoring," "alarm," "heart rate," "blood pressure," "follow-up," "smartphone," and "Bluetooth." In the event of identifying instances that had not previously been coded, the section was highlighted and coded using the aforementioned analysis method. The keywords used for searching the transcripts were chosen because they had either been previously identified in relation to an ideal monitoring feature for a dialysis device [97], or during the first stage of the deductive analysis. Lastly, to ensure all instances had been correctly identified, all transcripts were carefully read again. During the coding and analysis of the interviews, the author had weekly meetings with a research advisor where the coding results were compared, and discrepancies were discussed until a coding agreement was reached. To represent the results, each category was placed based on the analysis in a table that displayed the total number of comments that fell under each category along with an exemplary quotation from either a patient or a care partner (section 5.2).

To increase the validity of the qualitative analysis, five criteria of trustworthiness were considered: (1) credibility (how the data is interpreted and presented), (2) dependability (consistency of findings across similar participants in similar conditions), (3) confirmability (the data represents true responses from participants and avoids incorporating the researcher's biases), (4) transferability (the findings can be applied to other populations), and

(5) authenticity (the essence of each participant's experience is presented in a faithful manner; [34]). First, to ensure credibility, a reliable and well-known method for content analysis as described by [92, 51] was adopted. In addition, at each of the recruitment locations, the interviewer sought to build a rapport with the interviewees by creating a friendly, safe, and empathetic atmosphere. The participants were given as much time as needed to answer each question, and they were allowed to share their thoughts and experiences to the extent to which they felt comfortable. This was purposely done to achieve rich and detailed data. The data were then analyzed following the aforementioned steps of content analysis. Second, to help ensure the dependability of the study, frequent revisions and member checks where the coding process was reviewed and confirmed. Third, confirmability was ensured with the researchers' long-term engagement in the development of a wearable dialysis device that meets users' needs. Fourth, authenticity is demonstrated by presenting keywords and quotations taken directly from participants and showing how the quotations relate to each of the identified categories. Fifth, by including the descriptions of the population under study, the extent to which the findings can be transferred to other user groups may be inferred.

3.2.2 Quantitative Analysis

Descriptive Analysis

The quantitative analysis included descriptive statistical methods of numerical responses to demographic and background questions and numerical responses to rating questions of participants' attitudes [59]. (Tables 3.1, 3.2, 3.3).

Friedman Analysis

A non-parametric Friedman analysis was used to analyze rank-ordered data [66] of participants' responses. More specifically, this method was used to analyze participants' responses to proposed design types for the wearable hemodialysis device (section 4.2.1), ratings of ideal attributes of a wearable hemodialysis device (section 4.2.2), and ratings of ideal physical locations to carry a vascular connection device (section 4.3.1).

The rankings of the data were coded inversely, meaning that the higher the number

assigned, the more preferred the design type was or the more important the design attribute was considered. In the event of the Friedman analysis showing a statistically significant difference in ranking responses (p <0.05), an effect size assessing agreement among the participants was reported using Kendall's coefficient of concordance [105]. Then, a pair-wise Wilcoxon test was conducted, a non-parametric test to compare paired data, with a Bonferroni method to adjust for family-wise inflated Type I error [220, 24]. The analysis of ranking data was performed using R Statistical Software (version 4.2.1 (2022-06-23)) [166].

Exploratory Factor Analysis

Exploratory Factor Analysis (EFA) was conducted to explore the underlying structure among seven selected human factors design principles; ease of use, ease of connection, comfort, compactness, invisibility, safety, and accuracy. The analysis was performed using R Statistical Software (version 4.2.1 (2022-06-23)) [166] and the psych package [171].

The technique implies that measured variables are in some way influenced by another underlying attribute that cannot be directly measured. Such underlying attributes are called factors or latent variables [199, 213].

Conducting EFA requires five general steps; data examination, choosing a factor extraction method, setting factor extraction criteria, setting factor rotation criteria, and factor interpretation [222].

The first step of data examination involves deciding data suitability for factor analysis. In doing so, a Kayser-Mayer-Olkin (KMO) test is recommended to examine data sampling adequacy with values greater than 0.5 indicating good suitability [100, 187, 222]. Then, correlation adequacy is examined through Bartlett's test of sphericity [11]. Bartlett's test of sphericity tests the null hypothesis that the data correlation matrix is an identity matrix. An identity matrix indicates the variables are unrelated, implying no underlying structure. A significant Bartlett's test (p <0.05) thus indicates the detection of some underlying relations that in return concludes data suitability for factor analysis.

The second and third steps in conducting EFA involve determining the number of factors to retain for analysis. Research suggests that Principal Component Analysis and Parallel

Analysis are the most commonly used methods to extract and determine the number of factors particularly when there is no prior theory behind the factor structure [57]. While Principal Component Analysis is a non-parametric way of detecting the number of underlying main components in a dataset [186], Parallel Analysis is a statistical technique to determine how many of the identified main components to retain. Parallel Analysis is based on a Monte Carlo simulation where the simulation replicates the eigenvalues of a randomly generated dataset with equal dimensions as the original dataset. Then, the mean and standard deviation of the replicated eigenvalues along with the 95th percentile are calculated (95th percentile = mean + 1.65SD) to form the basis for which eigenvalues from the original dataset are compared. The number of eigenvalues exceeding the 95th percentile of the simulated eigenvalues is then used as the number of factors to be included in the factor analysis [89].

Once the decision on the number of factors to retain has been made, the factor structure of the data is established. Establishing factor structure can be done in two ways, either through an orthogonal rotation or oblique rotation. Orthogonal rotation produces a factor structure of uncorrelated factors while oblique rotation allows factors to correlate. Deciding on which method to use depends on the objective of each study [222].

The final step in conducting EFA involves interpreting the extracted factors. The researcher examines the variables and identifies the shared attributes among the variables. Lastly, the factors are labeled based on the shared attribute and theoretical conceptualization [222].

Structural Equation Modeling

Structural equation modeling (SEM) was conducted to explore the relationship between users' characteristics, their ratings of selected human factors design principles, and five proposed designs of a wearable hemodialysis device. The analysis was performed using the lavaan package in R [174, 166].

The statistical modeling technique of SEM has many advantages over other modeling approaches. SEM combines and extends multiple statistical techniques including factor

analysis and general linear models (GLM) that include multiple regressions [151, 27]. SEM also allows for the hypothesized testing of mediation, where the same variable, either an observed or latent variable, can simultaneously be a predictor or an outcome. Also, while traditional techniques, including GLMs, assume that observed variables are measured without any error, SEM with latent variables estimates and removes measurement error [118]. As a result, SEM gives more accurate parameters for estimating the relationships between variables [177].

Building an SEM requires the consideration of six main steps; model specification, validation and identification, data preparation, estimation, potential re-specification, and interpretation [111]. The first step of specification includes building the structural components of the model in line with the hypothesized relationships among variables. The proposed model in this research is shown in Figure 7.1 and examines the relationship among users' demographic factors, human factors design principles for wearable medical devices, and five proposed design types of a wearable hemodialysis device. The model shows the latent factor structure of the human factors design principles where the preceding section provided the foundation for the grouping of the human factors design principles through EFA. Latent variables in the model are represented by a circular shape with arrows departing from them towards a measurement variable whereas measurement variables have only arrows directed toward them. A variable in the model is considered to be exogenous if arrows are only departing from the variable (demographic factors) and endogenous if at least one arrow is directed towards the variable (design types). Epsilon 1 to Epsilon n represents the error terms for the latent variables representing human factors design principles. Epsilon 1,1 to Epsilon n,n represents the error term for the latent indicator variables.

The second step in building an SEM considers model validation and identification. A full SEM with latent variables comprises a measurement model and a structural model. Before modeling the relationships between all variables in the SEM, the measurement model needs to be validated. The validation of the measurement model is done through confirmatory factor analysis that considers three criteria; unidimensionality, validity, and reliability of the latent variables [8]. First, unidimensionality is achieved when all variables have a loading greater than 0.5 on a latent variable [8]. Validity, or the ability of the variables to mea-

sure the same underlying concept, is concluded with three measures; convergent validity is achieved when all variables in the measurement model are statistically significant, construct validity is achieved when model fit indices achieve required levels, and discriminant validity, or the ability of the measurement model to be free of redundant variables, is achieved when the correlation between independent variables does not exceed 0.85 [8]. Lastly, reliability, or the ability of a latent variable to measure an underlying concept, can be assessed by measuring composite reliability and average variance extracted. Composite reliability assesses the reliability and internal consistency of a latent variable while average variance extracted calculates the percentage of variation that is explained by a latent variable. To conclude reliability of a latent variable, composite reliability values should exceed a value 0.6 while the average variance extracted should be greater than 0.5 but is acceptable at 0.4 given the composite reliability level has been reached [8, 63].

Model identification is needed to derive unique estimates for the model parameters. Model identification can be done using a two-step rule [23]. The two-step rule first requires the SEM to be specified as a confirmatory factor analysis (CFA) model, also referred to as a measurement model, with all possible associations between variables. The first identification step includes having at least two indicators per each latent variable. The second step includes treating each latent variable as a measured variable and ensuring that the path directions are recursive. That is, there are no correlated error terms or loops in the structure. While researchers can establish identification using the two-step rule, most software packages indicate model identification upon computation.

Data screening and adequacy for SEM involves the examination of missing values, and outliers, and the assessment of multivariate data normality. A multivariate outlier is an extreme value on more than one variable showing atypical patterns. Locating multivariable outliers is an important step to help ensure unbiased estimates and can be done by calculating a Mahalanobis distance or the distance in variance units measured between an outlier score and sample mean [111]. Assessment of multivariable normality can be performed using Mardia's test of normality [111]. However, it is worth noting that multivariable normality is seldom achieved in practice with raw data [67]. As a result, data transformations may be needed along with choosing appropriate model estimation methods that use correction

methods for non-normal data [67, 111]

Establishing data adequacy also requires consideration of sample size. SEM is generally considered a modeling technique requiring large sample sizes. Large sample sizes are needed to avoid biased parameter estimates and making wrong conclusions regarding the fitness of the model[111]. However, there is currently no consensus among researchers on the parameters that define the required sample size for SEM. While widely accepted minimum sample sizes are N = 100 - 200 [111], research also suggests that SEM can be meaningfully tested with sample sizes as small as N = 50 [91]. Some researchers argue that by using absolute sample size recommendations one overlooks the importance of considering the number of parameter estimations in the model. As a result, sample sizes in the form of the ratio of participants (N) to model parameters (q), N:q, have been recommended [94]. Still, no universal consensus exists on this ideal ratio. For example, Kline (2012) recommends a ratio of 10:1, while Bentler and Chou (1987) recommend a ratio of 5:1 [111, 15].

Once a model has been identified, computations for the estimated model parameters can be performed. Various estimation methods exist for SEM each with its advantages and disadvantages. Choosing an estimation method for SEM generally depends on the data where the maximum-likelihood (ML) estimator is the most widely used method assuming continuous normal dependent variables. If the data shows violations of these assumptions, a more robust estimating method can be used to account for these violations. One such method includes using a full information maximum likelihood (FIML) estimator along with reconfirmation of the results through a bootstrapping method [8, 111]. The statistical method of bootstrapping involves resampling the data with replacement thousands of times, where each sampling procedure computes a sample mean and standard deviation. This procedure creates a new sampling distribution that more closely resembles a normal distribution [8].

During the simultaneous testing and estimation of the relationships between individual variables in the SEM, the overall relationship between all variables is also evaluated. This evaluation judges the overall model fit, or how well the model implied covariance matrix approximates the covariance matrix of the data. If the model fits the data poorly, the hypothesized relationship between the variables can be rejected [111]. In that sense, SEM is a disconfirmatory approach where researchers can reject poor models, but cannot confirm

the existence of good models. Researchers are, however, able to assess how well a proposed SEM model fits the data and make grounded inferences. Although there is currently no established universal agreement on what constitutes a good model fit, several guidelines have been recommended. Awang (2012), recommends using three categories of model fit: 1) the absolute model fit indices of Chi-square [217], Root Mean Square of Error Approximation (RMSEA) [26], and Standardized Root Mean Square of Residuals (SRMR) [93], 2) the incremental model fit indices of Comparative Fit Index (CFI) [93] and Tucker-Lewis Index (TLI) [14], and 3) the parsimonious fit index of Chi-square/degrees of freedom [134]. Determining the fitness of the model, the following acceptance criteria are widely used: Chi-square with a p-value > 0.05, RMSEA < 0.08, SRMR < 0.08, CFI and TLI > 0.9, and a parsimonious fit < 3.0. If a model fails to meet the acceptance criteria, researchers can carefully consider re-specifying their model in line with theory or examine data-driven modification indices to improve the model fit.

The last step in SEM is parameter evaluation and interpretation. Guidelines on the best reporting practices encourage reporting both unstandardized and standardized estimates of coefficients to aid interpretation [101]. The structural equation modeling and analysis was performed using R Statistical Software (version 4.2.1 (2022-06-23)) [166] and the lavaan package [174].

3.3 Study Population

3.3.1 Primary Study Population

Table 3.1: Demographics of the primary study population. Education* (1=high school, 2=associate's or college, 3=bachelor's, 4=master's, 5=doctoral)

Characteristic	Patients (n=24)	Care partners (n = 12)
Age, (years)		
Mean (SD)	65.5 (8.67)	64.25 (9.44)
95% CI	(59.01, 69.59)	(62.03, 68.97)
Gender, no. (%)		
Male	24 (100)	1 (8)
Female	0 (0)	11 (92)
Ethnicity, no. (%)		
Black	11 (46)	7 (58)
White	9 (37)	2 (17)
Other (e.g., Asian, Hispanic)	4 (17)	3 (25)
Education*		
Median	2	2
Impairment, no. (%) (Visual, Hearing, Deftness)		
Yes	16 (67)	4 (33)
No	8 (33)	8 (67)
Experience with hemodialysis and/or peritoneal dialysis, no. (%)		
Yes	22 (92)	10 (83)
No	2 (8)	2 (17)
Familiarity with wearable medical devices (1=very unfamiliar, 5=very familiar)		
Median	1.5	2

3.3.2 Secondary Study Population

Table 3.2: Demographics of the secondary study population. Education* (1=high school, 2=associate's or college, 3=bachelor's, 4=master's, 5=doctoral

Characteristic	Patients (n=16)	Care partners (n = 7)
Age, (years)		
Mean (SD)	60.64 (15.51)	65.86 (15.06)
95% CI	(52.23, 66.12)	(54.29, 74.46)
Gender, no. (%)		
Female	10 (62.5)	4 (57.1)
Male	6 (37.5)	2 (28.6)
Other	0 (0)	1 (14.3)
Race, no. (%)		
Asian	2 (12.5)	2 (28.6)
Black	3 (18.8)	0 (0)
White	8 (50)	4 (57.1)
Other	3 (18.8)	1 (14.3)
Ethnicity, no. (%)		
Hispanic or Latino	2 (12.5)	0 (0)
Not Hispanic or Latino	10 (62.5)	5 (71.4)
Other specified	4 (25)	2 (28.6)
Education.* Patients (n = 15), Care partners (n = 7)		
Median	2	3
Sight impairment, no. (%). Patients (n = 15), Care partners (n = 7)		
Yes	1 (7)	0
No	14 (93)	7 (100)
Deafness, no (%). Patients (n = 12), Care partners (n = 7)		
Yes	1 (8)	0 (0)
No	11 (92)	7 (100)

Table 3.2 continued from previous page

Characteristic	Patients (n=16)	Care partners (n = 7)
Physical disabilities, no. (%). Patients (n = 15), Care partners (n = 7)		
Yes	7 (47)	2 (29)
No	8 (53)	5 (71)
Current dialysis help, no. (%)		
Yes	6 (37.5)	5 (71.4)
No	10 (62.5)	2 (28.6)
Expected mobile hemodialysis help, no. (%), patients (n = 15), care partners (n = 6)		
Yes	6 (40)	4 (67)
No	9 (60)	2 (33)

Table 3.3: Dialysis and vascular access experiences. (Secondary study participants).

Characteristic	Patients (n=16)	Care partners (n = 7)
Dialysis experience, no. (%) Patients (n = 15), Care partners (n = 7)		
In-center	15 (100)	5 (71)
Home hemodialysis	3 (20)	4 (57)
Peritoneal dialysis	3 (20)	2 (29)
Portable dialysis	3 (20)	4 (57)
Catheter experience, no. (%)		
Yes	10 (62.5)	3 (42.9)
No	6 (37.5)	4 (57.1)
Catheter location, no.		
Chest	6	3
Stomach	2	0
Arm	1	0
Neck	0	1
Min duration	7 days	8 months

Table 3.3 continued from previous page

Characteristic	Patients (n=16)	Care partners (n = 7)
Max duration	5 years	10 years
Who connects the catheter?, no.		
Technician at center	6	2
Self	2	0
Fistula experience, no. (%)		
Yes	11 (68.8)	4 (57.1)
No	5 (31.3)	3 (42.9)
Fistula location, no,		
Upper Right arm	1	1
Upper Left Arm	5	1
Forearm	1	
Right lower arm	1	1
Right wrist	2	
Left Arm	1	
Right Arm		1

3.3.3 Clinicans Study Population

A total of 30 nephrologists across 20 U.S. states and 32 registered nephrology nurses across 16 U.S. states were recruited for this study. The nephrologists were all members of the American Society of Nephrology (ASN) and the nephrology nurses were all members of the American Nephrology Nurses Association (ANNA). With 20,472 global members, ASN is a non-profit, tax-exempt alliance for kidney health. The mission of ASN (2023) is to "elevate care by educating and informing, driving breakthroughs and innovation, and advocating for policies that create transformative changes in kidney medicine throughout the world." Over the last decade, ASN has sought to stimulate innovation in kidney care. Their efforts include encouraging innovators in nephrology to include users early and iteratively throughout their design process. Since its establishment as a nonprofit organization in 1969, ANNA's mission

is to improve members' lives through education, advocacy, networking, and science. ANNA has a membership of over 8,000 registered nurses and healthcare professionals who practice in all areas of nephrology. Participants' demographic information is displayed in Table 3.4.

Table 3.4: Demographics and clinical experience of participants (clinicians).

Characteristic		Nurses (n = 32)	Nephrologists (n = 30)
Age, years			
	Mean (SD)	50.88 (10.30)	52.67 (7.76)
	95% CI	(47.31, 54.44)	(49.89, 55.44)
Gender identifying, no. (%)			
	Male	2 (6.25)	22 (73.3)
	Female	30 (93.75)	8 (26.7)
	Other	0 (0)	0 (0)
Race, no. (%)			
	Black	2 (6.25)	2 (6.7)
	White	21 (65.63)	13 (43.3)
	Asian	7 (21.88)	11 (36.7)
	Other	2 (6.25)	3 (10.0)
	Prefer not to say	0 (0)	1 (3.3)
Years in practice			
	Mean (SD)	21.33 (12.75)	20.73 (8.67)
	95% CI	(17.11, 25.54)	(17.63, 23.84)
Therapy experience, no. (%)			
	In-center hemodialysis	28 (87.5)	30 (100)
	Peritoneal dialysis (PD)	21 (65.63)	30 (100)
	Home hemodialysis	16 (50.0)	29 (96.67)
	Acute dialysis (PD and hemo)	10 (31.25)	1 (3.33)

Table 3.4 continued from previous page

Characteristic	Nurses (n = 32)	Nephrologists (n = 30)
Patients on therapy (combined no.)		
In-center hemodialysis	3299	2966
Peritoneal dialysis (PD)	736	569
Home hemodialysis	270	144
Other (please specify)	0	0
Vascular access experience. no. (%)		
Catheter	31 (96.88)	30 (100)
Fistula	31 (96.88)	30 (100)
Graft	31 (96.88)	30 (100)
Other (Hero graft, Ellipsys)	3 (9.38)	2 (6.67)
Portable dialysis device(s) experience, no. (%)		
Yes	10 (31.25)	9 (30.0)
No	22 (68.75)	21 (70.0)
NxStage	9 (28.13)	8 (26.67)
Fresnius	2 (6.25)	0 (0)
Other (Homechoice, Amia, Redy)	6 (18.75)	3 (10.0)

Chapter 4

PATIENTS' AND CARE PARTNERS' NEEDS AND PERSPECTIVES OF A WEARABLE HEMODIALYSIS SYSTEM

The goal of this chapter is to answer research question R1 by characterizing patients' and care partners' perspectives of a wearable hemodialysis system. First, section 4.1 characterizes the use specifications of a wearable hemodialysis system by exploring the challenges patients and care partners face with current hemodialysis treatments (section 4.1.1), expected use environment of a wearable hemodialysis system (section 4.1.2), travel motivations and related concerns (sections 4.1.3 and 4.1.4), and expected use scenarios (section 4.1.5). Then, section 4.2 aims to characterize patients' and care partners' perspectives of a wearable hemodialysis device, while section 4.3 aims to characterize patients' and care partners' perspectives of a vascular connection device. For both devices patients' and care partners' perspectives were gathered on ideal design forms (sections 4.2.1, and 4.3.1), ideal features of the device (sections 4.2.2, and 4.3.2), and potential challenges related to the device use (sections 4.2.3, and 4.3.3). Additionally, this study explored patients' and care partners' perspectives regarding acceptable durations in connecting a vascular connection device to a wearable hemodialysis device (section 4.3.4). The findings from this chapter help guide initial concept developments of a wearable hemodialysis system following patients' and care partners' needs and perspectives.

4.1 Use Specifications of a Wearable Hemodialysis System

To understand users' need for an alternative mode of hemodialysis treatments, this section explores if patients and care partners experience any physical and or mental challenges in relation to current dialysis treatments (section 4.1.1). Then, patients' and care partners' perspectives of intended use environments and wearable hemodialysis use scenarios were explored (section 4.1.2). By identifying current challenges that patients and care partners experience along with their envisioned usage, developers can better ensure that their designs

accommodate the conditions of different environments and varying needs of users.

4.1.1 Challenges of Current Hemodialysis Systems

To explore the challenges of current hemodialysis treatments, the participants were asked if they experienced any physical or mental challenges in relation to their (their patient partners') current hemodialysis treatments. Inductive content analysis of participants' responses indicates that current hemodialysis treatments and procedures cause challenges to several of the participants, both physically and mentally.

In terms of physical challenges experienced, most participants talked about how current systems restrict patients' mobility during treatment. Current systems require the patient to be connected to a stationary device limiting them in doing activities and going about their daily lives. This also caused some participants boredom during treatment. The participants also talked about patients' being uncomfortable in their chairs while receiving treatment. Also, patients' restricted mobility hindered patients' ability to go to the restroom while receiving treatment. In terms of physical symptoms, participants mentioned experiencing cramping, pain, and weakness. Figure 4.1 displays the percentage of participants' responses under each identified category of participants' physical challenges. Immobility refers to patients' restricted mobility during treatment caused by the dialysis device. Mobility impairment refers to patients' physiological condition limiting their mobility.

Analysis of participants' responses of experienced mental challenges related to current hemodialysis treatments reveals that some participants do experience mental challenges. Most frequently, the participants talked about feeling frustrated with current hemodialysis treatments, experiencing stress and depression, and feeling anxious, fearful, and angry. Some participants talked about the mental challenge of frequent needle sticks and enduring pain, and some care partners talked about experiencing a high workload and lack of sleep. Figure 4.2 displays the percentage of participants' responses under each identified category of participants' physical challenges.

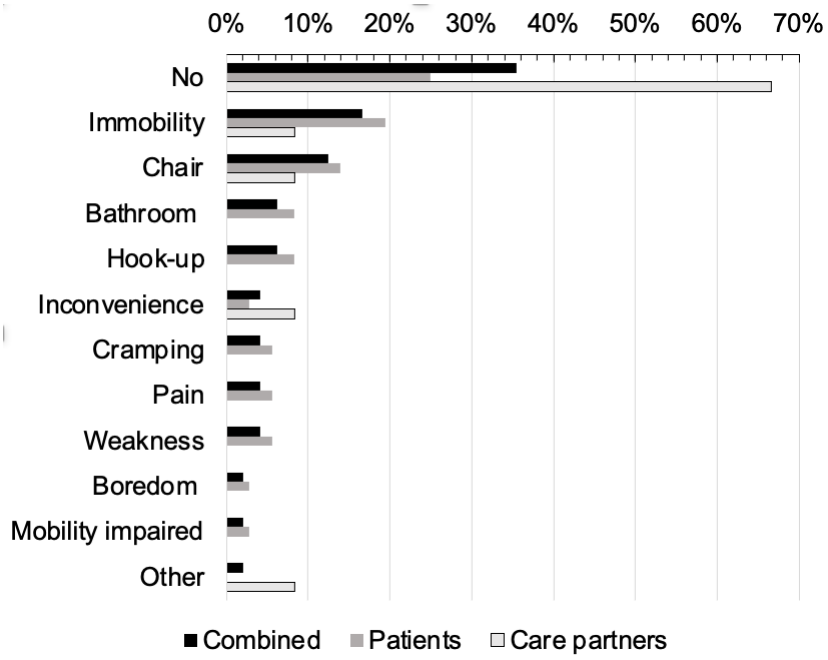

Figure 4.1: Percentage of participants' total responses under identified categories of the physical challenges the participants experience in relation to patients' current dialysis treatments. (Primary study population).

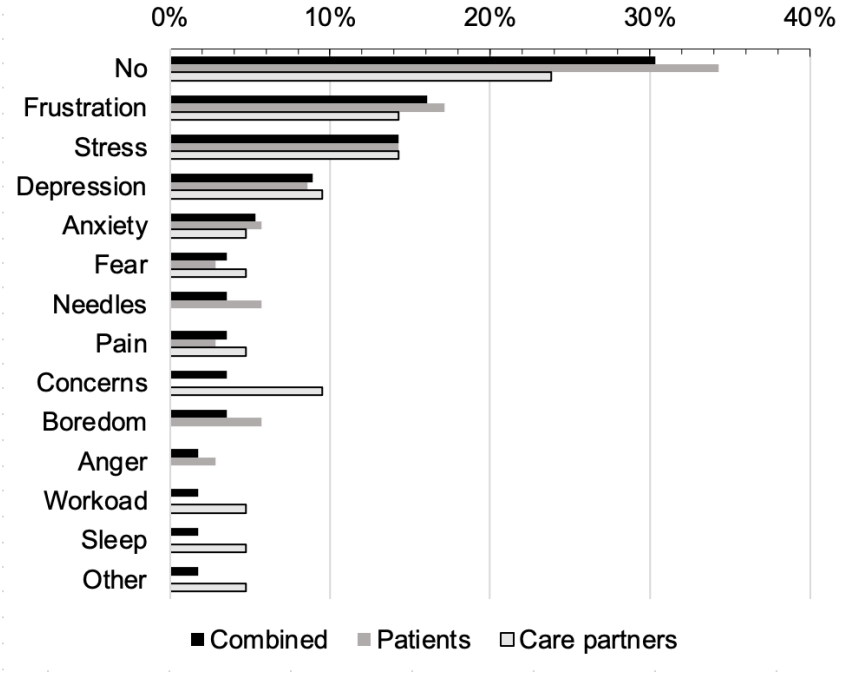

Figure 4.2: Percentage of participants' total responses under identified categories of the mental challenges the participants experience in relation to patients' current dialysis treatments. (Primary study population).

4.1.2 Use Environment

An important aspect of human factors engineering is to understand how people interact with technology. This interaction can vary across different use environments where external factors may affect user and device performance. As such, it is important to develop an understanding of intended use environments so the final product is tailored to meet users' needs across intended use environments and scenarios.

To understand intended use places and environments of a mobile hemodialysis device the participants were asked to state their willingness to use a hemodialysis device in different places and environments. Figure 4.3 displays the frequency of patients' willingness to use a hemodialysis device in different environments where section A shows responses to proposed use environments and section B shows responses to additional environments proposed by the

participants. The results show that most participants intend to use a hemodialysis device at home or at the homes of family members of friends or at a hotel while traveling. Most participants also indicated their willingness to use a hemodialysis device while riding in a car or at their work place, and many participants indicated willingness to use a hemodialysis device while camping outdoors in nature. The results show mixed findings when the participants were asked for their willingness to use a dialysis device in public places. For example, while some participants indicated their willingness to use a hemodialysis device at their respective workplaces, at hotels, or while camping, the same participants stated unwillingness to use a dialysis device at public parks or at restaurants. Some participants initially indicated unwillingness to use a hemodialysis device in general public places but later indicated their willingness to use a hemodialysis device while traveling on an airplane or on a cruise ship. When the participants were asked to elaborate on their responses, the findings suggest that the participants are willing to use a hemodialysis device in diverse places and environments yet are concerned about heightened risk of infection, particularly in public environments.

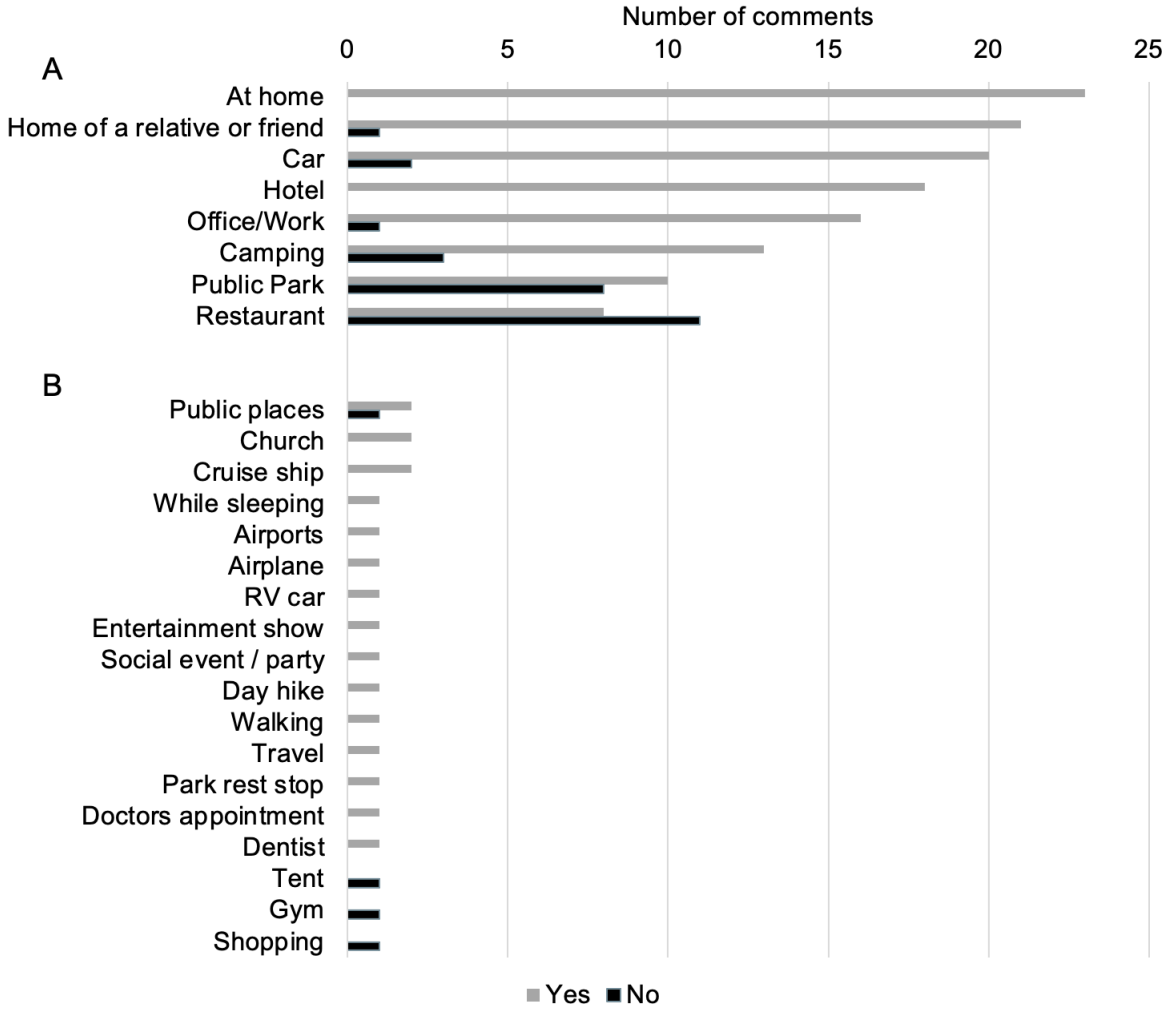

Figure 4.3: Frequency of participants' willingness to use a wearable dialysis device across places and environments. section A shows responses to places and environments proposed by researcher. section B shows responses to places and environments additionally proposed by patients and care partners. (Secondary study population).

4.1.3 Travel Motivations

As the wearable hemodialysis system aims to overcome the limitations of current hemodialysis systems by providing an ESRD patient with greater mobility and flexibility of travel, the participants were asked to share motivations and reasoning for traveling. This question

also aimed to better understand potential use environments. As described in section , the participants were given ten proposed travel reasons to choose from with the opportunity to add additional responses if needed. The participants were further allowed to select multiple motivational reasons. Figure 4.4 summarizes the participant's results indicating that the highest-ranking motivation to travel for both the patients and the care partners was to visit family or friends, followed by escape or relaxation. The third-highest rankings for travel motivation for both the patients and the care partners were outdoor recreation and scenic or natural attractions. The travel motivations, warmer climate and socialize or dating, received one responses from each of the patients and care partners, and sports events ranked the lowest with one response from one care partner. None of the participants mentioned additional reasons for traveling.

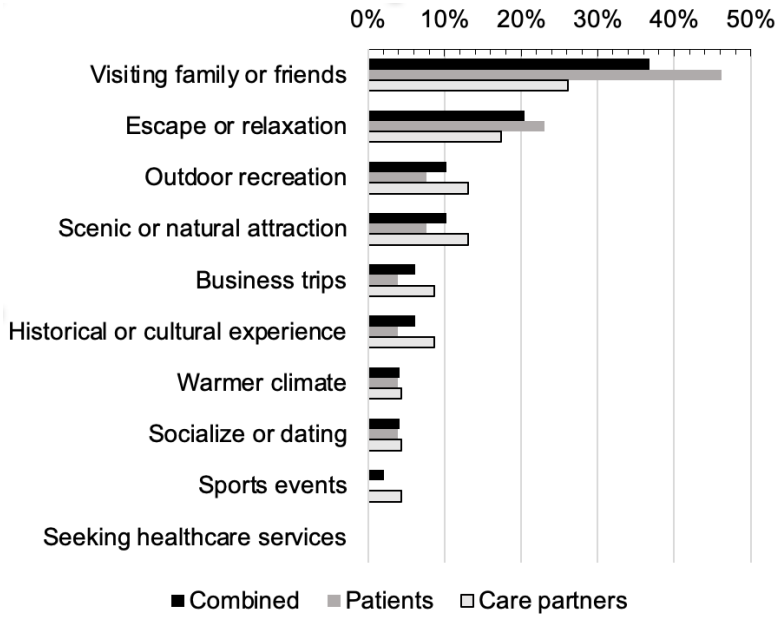

Figure 4.4: The percentage of comments under identified categories of travel motivations. (Secondary study population.)

4.1.4 Travel Concerns

To better understand the barriers that dialysis patients experience, the participants were asked to share any concerns they had experienced with respect to planning overnight travel. Most participants indicated that dialysis treatments either completely hinder or challenged their freedom of traveling. Some participants were worried about not having access to dialysis treatments while traveling, and others indicated that the logistics around scheduling treatments was overwhelming, and the need of bringing sufficient and necessary supplies and devices was seen as inconvenient. The participants further indicated feeling uncomfortable having to schedule treatments in an unfamiliar dialysis center and thus chose to restrict their days of travel with additional concerns of being back home in time for the next dialysis session. The identified categories of participants' travel concerns are shown in Table 4.1.

Table 4.1: Identified categories with exemplary quotations in relation to participants' travel concerns. CP = care partner, P = patient. (Secondary study population).

Categories	Formulated Description	Number of Comments
Dialysis	Concerns related to needing treatment.	5
Exemplary quotation	"I don't travel because of dialysis." -P3	
Logistics	Complicated logistics of bringing dialysis supplies or scheduling treatment elsewhere.	5
Exemplary quotation	"The logistics of bringing sufficient dialyssi supplies and the inconvenience of lugging a bag carrying 25 lb machine in and out of the plain and airposrt." -P33	
Accessibility	Lack of access to treatment at travel destination.	2
Exemplary quotation	"Access to dialysis is the only thing that prohibits overnight travel. Patient did daytrips only." -CP3	

Table 4.1 continued from previous page

Categories	Formulated Description	Number of Comments
Trust	Lack of trust in treatment anywherer else than at patients' local center.	2
Exemplary quotation	"Quality of care of a center away from home, adherence to sterile technique, willingness of the unit to comply with our wishes because of our extensive experience." -CP10	
Time	Insufficient time to travel due to needed treatments.	2
Exemplary quotation	"I can only be away from my home for 2 days since I do home hemo." -P20	
Health condition	Concerns over physical abilities affecting travel.	2
Exemplary quotation	"Not falling down." -P24	
Medications	Needed medication.	2
Exemplary quotation	"Medication." -P12	

4.1.5 Use Scenarios

As the wearable hemodialysis system aims to overcome the limitations of current hemodialysis systems by providing an ESRD patient with greater mobility and flexibility of travel, the participants were also asked what activities they, or their patient partner, would like to do while wearing a hemodialysis device. This question aimed to better understand the intended use scenarios of the system in relation to patients' mobility.

Figure 4.5 shows the specific tasks that interviewees mentioned, which are sorted into seven categories representing the total number of comments participants made about each

particular task type. The number of comments illustrated in Figure 4.5 is placed inside the parentheses at the end of each word related to the contents. First, everyday activities were the most commonly mentioned activities (35.6%). Everyday activities are defined as basic functions that the patient needs in order to thrive, such as bathing, dressing, personal hygiene, using the toilet, feeding, and walking [103] and further include activities that are needed in order to live independently such as preparing meals, working, household chores and grocery shopping [103]. The detailed daily activities are illustrated in Figure 4.5 under the "everyday" category. Second, social-related comments were the second-most mentioned activities (16.1%). Social activities are defined as activities in relation to patients longing to spend time with friends and family or go to community-based places such as restaurants or movie theaters. Third, physical activity (14.9%) was also commonly mentioned, with activities defined as activities in relation to physical energy being used with the intention of maintaining or improving physical fitness. Fourth, interviewees indicated needing a wearable dialysis device that accommodates their travels (11.5%), which defines activities in relation to reaching destinations without needing to consider the time commitment of current dialysis procedures. Fifth, interviewees mentioned wanting more freedom (9.2%), and longing to take control over their own time schedule and limitations. Finally, interviewees mentioned leisure activities (8.1%) that are related to patients' cognitive activities or productivity without physical energy being used and others (4.6%) include trivial comments that do not fall in the above categories.

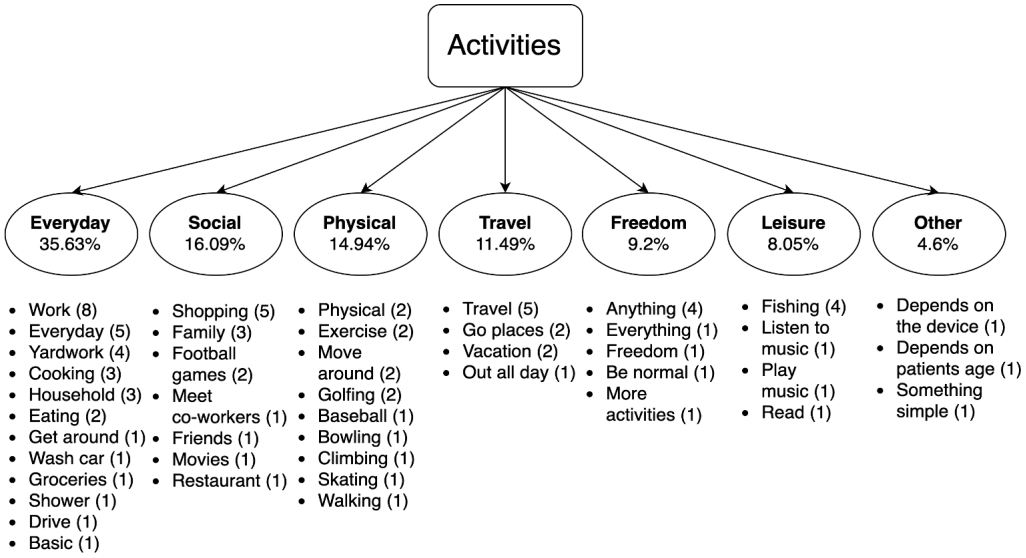

Figure 4.5: Identified categories of patients' activities while using a wearable dialysis device. Keywords mentioned by the patients and care partners are shown under each category. The number in parenthesis indicates how many times each keyword was mentioned.
(Primary study population).

4.2 Users' Needs and Perspectives of a Wearable Hemodialysis Device

The goal of this chapter is to answer research question R2 by characterizing the design requirements for monitoring and training procedures for a wearable hemodialysis device.

The work of this section is comprised of three objectives. First, to inform initial form factors of a wearable hemodialysis device, patients and care partners were asked to indicate their most preferred physical location for wearing a mobile hemodialysis device (section 4.2.1). They were also asked to visualize and describe their most ideal mobile hemodialysis device (section 4.2.1) and to rank in order of preference five proposed design types of a wearable hemodialysis device (section 4.2.1). Secondly, to gather ideal device-related attributes, patients and care partners were asked to name the most important features of a wearable hemodialysis device (section 4.2.2) and rank in order of importance seven selected human factors design principles for wearable medical devices (section 4.2.2). Lastly, to gain insight into potential challenges of a wearable hemodialysis device, the patients and care partners

were asked to describe any potential concerns they may have in association with a wearable hemodialysis device (section 4.2.3). The findings from this section may help inform initial design objectives to ensure that new wearable hemodialysis devices are designed following patients' and care partners' needs and preferences.

4.2.1 Ideal Design Forms of a Wearable Dialysis Device

Visualizing the Designs of the Most Ideal Wearable Hemodialysis Device

The participants were asked open-endedly to think about and describe their most ideal wearable dialysis device. Since it was expected that some participants might have difficulty answering this question, the participants were allowed to skip this question if necessary. Ultimately, 17 patients (of 24) and 9 (of 12) care partners replied to this question, providing various ideas about what the ideal wearable dialysis device would look like. Inductive content analysis of participants responses indicates that their visions include three main categories: design suggestions in relation to wearing the device on a particular physical location and design suggestion without relation to a physical location (Table 4.2), and ideal attributes of the device (Table 4.3).

Both patients and care partners were found to describe their ideal wearable dialysis device as similar to current wearable medical devices such as portable oxygen machines or wearable insulin pumps. Patients envisioned a device that is flexible and comfortable to wear, adjustable with a strap or a belt around the waist, lightweight, and small. Patients further described the device as being simple to operate, easy to hook up to the bloodstream, presenting a low risk of infection, and easy to put on and take off as needed. Patients also wanted a device with a long-lasting battery that could easily be recharged similar to charging a cell phone and a device that could be hidden from the general public particularly by wearing the device under their clothing. Four patients envisioned carrying the device over their shoulder, three patients mentioned the device being located on their backs, three patients described the device as forming a belt placed at either the hip or around the waist, and one patient envisioned the device being worn on the upper body similar to wearing a vest. While care partners similarly imagined a lightweight and compact device, they also

envisioned a device that was designed in such a way that patients could easily reach and interact with the device without assistance from others but that they, as the care partners, could easily access the device if necessary. Two care partners described their ideal device as akin to "a cart with wheels," four care partners described a device that could be carried similarly to a shoulder bag using either a strap or a sling, and two care partners described a compact device that could be worn on a belt around the waist. Other descriptions included a backpack design (one care partner), a device somehow carried on the abdomen (one care partner), and a device carried on a wrist or an armband (one care partner). Table 4.2 displays the design suggestions from the participants and Table 4.3 displays the ideal attributes of participants' most ideal device along with related keywords or short phrases mentioned by the participants.

Table 4.2: Design suggestions of the most ideal wearable hemodialysis device. The number in the parenthesis indicates the number of design suggestions. (Primary study population).

Design suggestion in relation to a physical location.	
Patients (13)	**Care partners (11)**
Backpack	A wrist or arm band
Carry on back	Abdomen so patient does not have to bend
Carry on shoulder	Backpack
Formed to the hip	Belt
Over the shoulder	Compact on belt
Shoulder bag	Like man purse
Similar to a portable breathing machine over the shoulder	Similar to a portable breathing machine but on the back
Similar to a portable breathing machine	Similar to a portable breathing machine
Strap to the middle with belt	Sling over shoulder
Vest	Strap over shoulder
Waist belt	With a strap over the shoulder
Handheld	
Worn on back	
Design suggestions without relation to a physical location	
Patients (6)	**Care partners (2)**
A box	Cart on wheels
A wallet that fits into an ordinary pocket	Convenient with wheels
A plastic bag	
Made of plastic, can mold to your chest like body armor under clothing	
Velcro	
Insulin pump	

Table 4.3: Ideal attributes of the most ideal wearable hemodialysis device. The two number in the parenthesis indicates the number of associated keywords from patients and care partners respectively. (Primary study population).

Ideal attributes	Patients	Care partners
Operational Simplicity (7,5)	Easy hook-up, easy to put on/take off, easy to put together, simple	Does not require assistance, easy to reach, easy to access, easy for care partner to see, easy and simple to use
Small sized (5,1)	Compact, not bulky, small	Not bulky
Lightweight (4,4)	Lightweight, less than 8 lb	Lightweight, less than 5 lb, not heavy
Chargeable (4,1)	Battery operated, charge like a cell phone, lasting battery	Chargeable
Noticeability (4,1)	Clothes over device, does not protrude, hidden, invisible	Quiet, does not show under clothes,
Mobility (4,0)	Easy to transport, flexible, adjustable, freedom to move (not restricting)	-
Safety (2,0)	Low infection risk, can go in public without worry about being sterile	-
Durability (2,0)	Durable, protected	-
Efficacy and efficiency (1,1)	Get good dialysis	Efficient

Table 4.3 continued from previous page

Ideal attributes	Patients	Care partners
Monitoring (1,1)	Regular check-in at hospital	Something where patient can see level of dialysis
Treatment wear time (1,0)	Does not require long time to wear	-
Comfort (0,1)	Comfortable	-

Most Preferred Design Form of a Wearable Hemodialysis Device

After gathering unbiased design ideas from the primary study participants of the most ideal designs, five proposed design concepts were presented to the participants. The five design concepts included a backpack, a belt, a vest, a shoulder bag, and a distributed design (a model in which the various parts of the device are separated from one other on the body). The participants were asked to rank the designs in order of preference (1=most, 5=least). Determining the rankings of the five proposed design types, the data from the combined sample of patients and care partners were first analyzed. The results from a Friedman analysis of variance indicated that participants' preferences regarding design types were statistically different ($\chi^2 = 24.647$, df = 4, $p < 0.0001$)with a small effect size detected ($W = 0.176$). A pairwise Wilcoxon test, a non-parametric test to compare paired data, with a Bonferroni correction showed that the combined group of participants significantly preferred the belt and the vest over the shoulder bag and the distributed model.

Analyzing the responses from patients and care partners separately, the findings show that preferences regarding design types amongst the patients only were also statistically significantly different ($\chi^2 = 19.44$, df = 4, $p < 0.001$) with a small effect size detected ($W = 0.211$). Wilcoxon-Bonferroni post-hoc analysis indicated that the patients significantly preferred the belt and vest designs over the shoulder bag, and distributed model. Preferences among the care partners were also statistically significantly different ($\chi^2 = 11.013$, df = 4, $p < 0.05$) with a small effect size detected ($W = 0.229$), where the care partners preferred the vest design over a distributed design.

Preferred Physical Location for Carrying a Wearable Dialysis Device

To guide the initial designs and form factors of a wearable hemodialysis device, the participants were asked to state their preferences regarding where on the body they would ideally like to carry the device. Figure 4.6 shows the frequency of keywords for the preferred physical location for carrying a wearable hemodialysis device based on the responses of all interviewed participants (black), patients only (gray), and care partners only (white). The results show that most participants imagined that they would prefer a hemodialysis device carried on the back, followed by the waist and the shoulder.

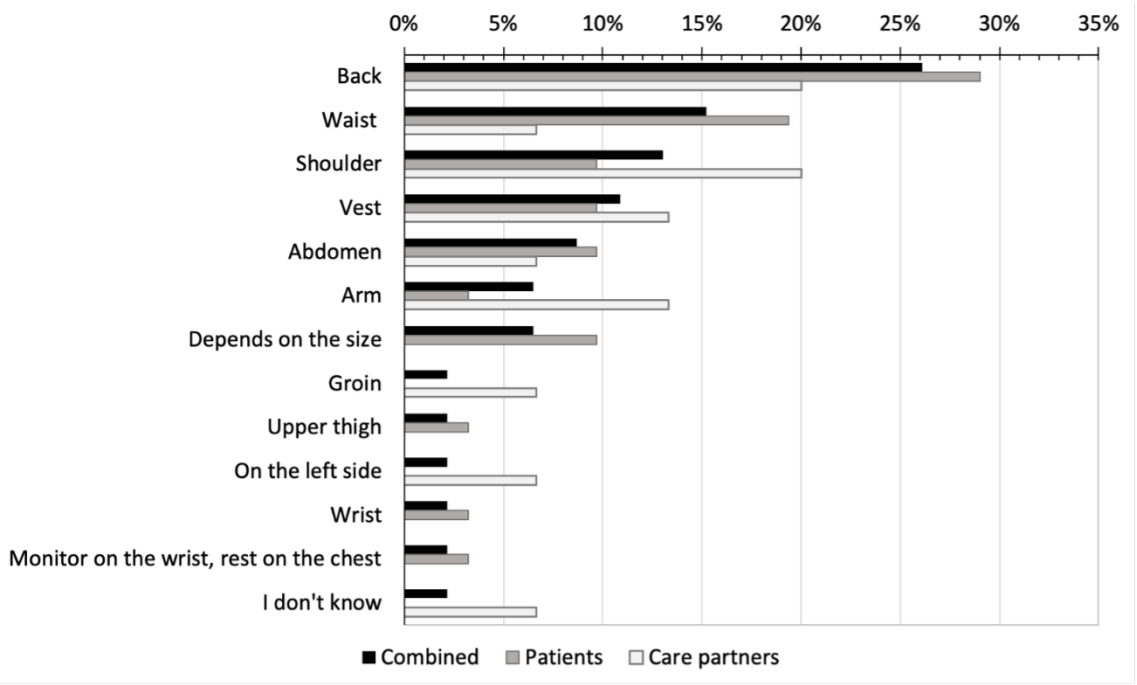

Figure 4.6: Percentage of participants' total responses under identified categories of preferred physical location for carrying the wearable dialysis device. (Primary study population).

4.2.2 Ideal Features of a Wearable Hemodialysis Device

Most Important Features of the Ideal Wearable Hemodialysis Device

Inductive content analysis of patients and care partners responses regarding their preferred features for a wearable dialysis device revealed 14 key categories as shown in Figure 4.7. In addition to the 7 pre-determined and device-related attributes, 7 of the 14 categories were formed based on participants' responses. Figure 4.7 shows the keywords that fell under each category. Representative quotations from patients and care partners regarding the most important features of a wearable dialysis device in Table 4.4. Patients and care partners identifying information is abbreviated. The letter L stands for a participant recruited from Louisville, N for one from Nashville, and S for one from Seattle; the letter P stands for a patient, and the letter C stands for a care partner. Responses that were at least one sentence in length were selected to illustrate the data; responses that were single keywords or lists of keywords were displayed in a figure.

Patients most frequently mentioned attributes related to operational simplicity, using language like "simple," "not too complicated," "easy to operate," and "easy to understand." Patients also remarked on the importance of being able to easily access the device while wearing it and having a device that was easy to both put on and take off of the body. In terms of connecting the device to the bloodstream, participants considered easy hook-up without needles as another user-friendly feature. Patients' second-most mentioned important features were related to the compactness of the device. Patients highlighted the importance of a lightweight and small device. The third-most frequently mentioned important features were related to the invisibility of the device. Patients indicated a preference for a device that would not draw attention to them or that could easily be hidden under clothing.

Care partners similarly mentioned the compactness of the device and specific design-related features as among the most important. Similar to patient responses, the care partners indicated the importance of the device being small and lightweight. Care partners also indicated that they preferred a design that would allow patients to bathe or shower independently and that could easily be observable by care partners when necessary. Care partners envisioned the ideal device as one that would give patients confidence and that could be

designed and manufactured in different styles based on the age or lifestyle of a patient. Safety and operational simplicity were care partners' second-most mentioned features. Care partners felt that the device should be safe against infections, accurate in terms of functionality, and secure in terms of placement on the body. Finally, care partners indicated they preferred a device that would be easy to use and easily accessible to patients, such that the care partners were not required to provide excessive assistance.

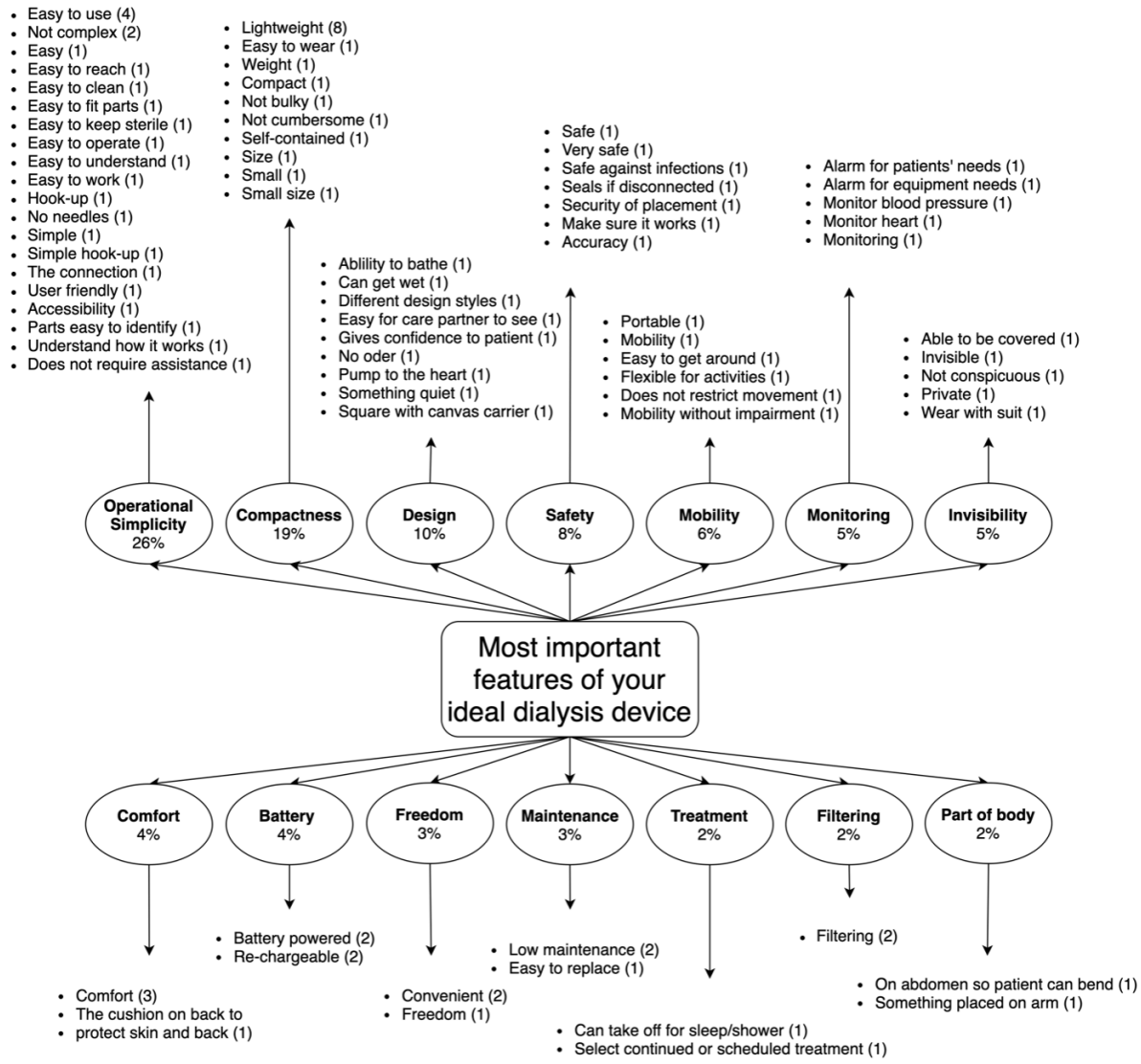

Figure 4.7: Categories of features of the ideal mobile hemodialysis device. Keywords are displayed under each category. The number in the parenthesis indicates how many times the keyword was mentioned by a participant. (Primary study population).

Table 4.4: Identified categories of ideal features of a wearable hemodialysis device along with exemplary quotations. (Primary study participants).

Categories	Exemplary quotations
	Patients
1. Operational simplicity	"All parts are easy to identify." -NP8 "Easy to operate." -LP9
2. Compactness	“Lightweight and easy to wear.” -SP4
3. Design	"Square with canvas carrier." -LP1
4. Safety	“Seals if disconnected with no possibility of bleeding out.” -SP5
5. Mobility	“Flexible (working in yard/car wash) and does not interfere with daily activities.” -NP2
6. Monitoring	“Monitors the heart.” -SP6
7. Invisibility	“Able to be covered." -LP12
8. Comfort	“Light cushion on the back to protect skin and back.” -LP1
9. Battery	"Battery operated and re-chargeable." -NP6
10. Freedom	-
11. Maintenance	“Easy to replace.” -LP13; "Should be low maintenance.” -SP5
12. Treatment options	“Could be used intermittently that is can take off for sleep or shower.” -LP10
13. Filtering	-
14. Part of body	"Something placed on the arm." -NP1
	Care partners
1. Operational simplicity	“Easy to use.” -NC1
2. Compactness	“Lightweight and easy to get around.” -LP6

Table 4.4 continued from previous page

Categories	Exemplary quotations
3. Design	“Different styles, like if it is for a kid it should have cartoon characters.” -LP2
4. Safety	“Safe against infections.” -NC3
5. Mobility	“Security of placement, mobility without further impairment.” -SC1
6. Monitoring	“Able to monitor the blood pressure while doing dialysis.” – LP003; "The device should contain an alarm to alert the patient to urgent medical attention and or equipment needs.” -SC4
7. Invisibility	-
8. Comfort	-
9. Battery	-
10. Freedom	"The convenience and the freedom." -SC3
11. Maintenance	-
12. Treatment options	“The mobile dialysis device should have at least two ways of dispensing treatment: continuous or scheduled for 2 days or as needed.” -SC4
13. Filtering	"Filtering is a must" -LP2
14. Part of body	"On the abdomen so patient does not have to bend." -NC2

Ratings of Ideal Attributes of a Mobile Hemodialysis Device

The primary study participants were asked to think about the qualities they considered important in a wearable dialysis device and rank seven device-related attributes—accuracy, ease of connection, comfort, safety, compactness (weight and size), ease of use, and invisibility—in order of importance (1=most, 7=least).

Friedman analysis of variance showed that participants' importance ranking of device related attributes were statistically different ($\chi^2 = 70.205$, df = 6, $p < 0.0001$) with a moderate effect size detected ($W = 0.366$). A pairwise Wilcoxon test, a non-parametric test to compare paired data, with a Bonferroni correction showed that accuracy was ranked more important than ease of connection, comfort, compactness, ease of use, and invisibility. Invisibility was found to be significantly less important than the other six attributes.

Analyzing rating responses from patients and care partners separately the results from Friedman analysis of variance showed a statistically significant difference in rating responses from both the patients and the care partners (($\chi^2 = 47.551$, df = 6, $p < 0.0001$) and ($\chi^2 = 26.182$, df = 6, $p < 0.0001$), respectively, both with moderate effect size detected ($W = 0.377$, and $W = 0.397$, respectively). Pairwise Wilcoxon-Bonferroni post-hoc analysis showed that the patients importance rankings mirrored the rankings of the combined group with accuracy ranking as more important than ease of connection, comfort, compactness, ease of use, and invisibility, and invisibility significantly less important than the other six attributes. Wilcoxon-Bonferroni post-hoc analysis for the care partners showed invisibility being less important than the other six attributes.

4.2.3 Potential Challenges of a Wearable Hemodialysis Device

Inductive analysis of participants' responses regarding concerning features of a wearable hemodialysis device revealed 14 key categories shown in Figure 4.8. Most frequently, the participants were concerned about how hard it would be to operate the device, how long the patients' would be required to wear the device, and if they were required to use needles to access the patients' bloodstream. The participants were also concerned about how large and how heavy the device would be, and concerned about malfunctioning of the device,

particularly in terms of false readings, breakdowns during treatment, and repair time. The participants also talked about their concerns in relation to the safety of the device where they were particularly concerned about patients' bleeding, patients developing blood clots and whether emergency respondents would know how to operate the device in a life threatening emergency. Other mentioned concerns included design considerations where the participants were concerned about the device having too many components and the risk of the device slipping of the patients' body. The detailed documentation of the 14 key categories and the keywords or short phrases that fell under each category are displayed in Figure 4.8.

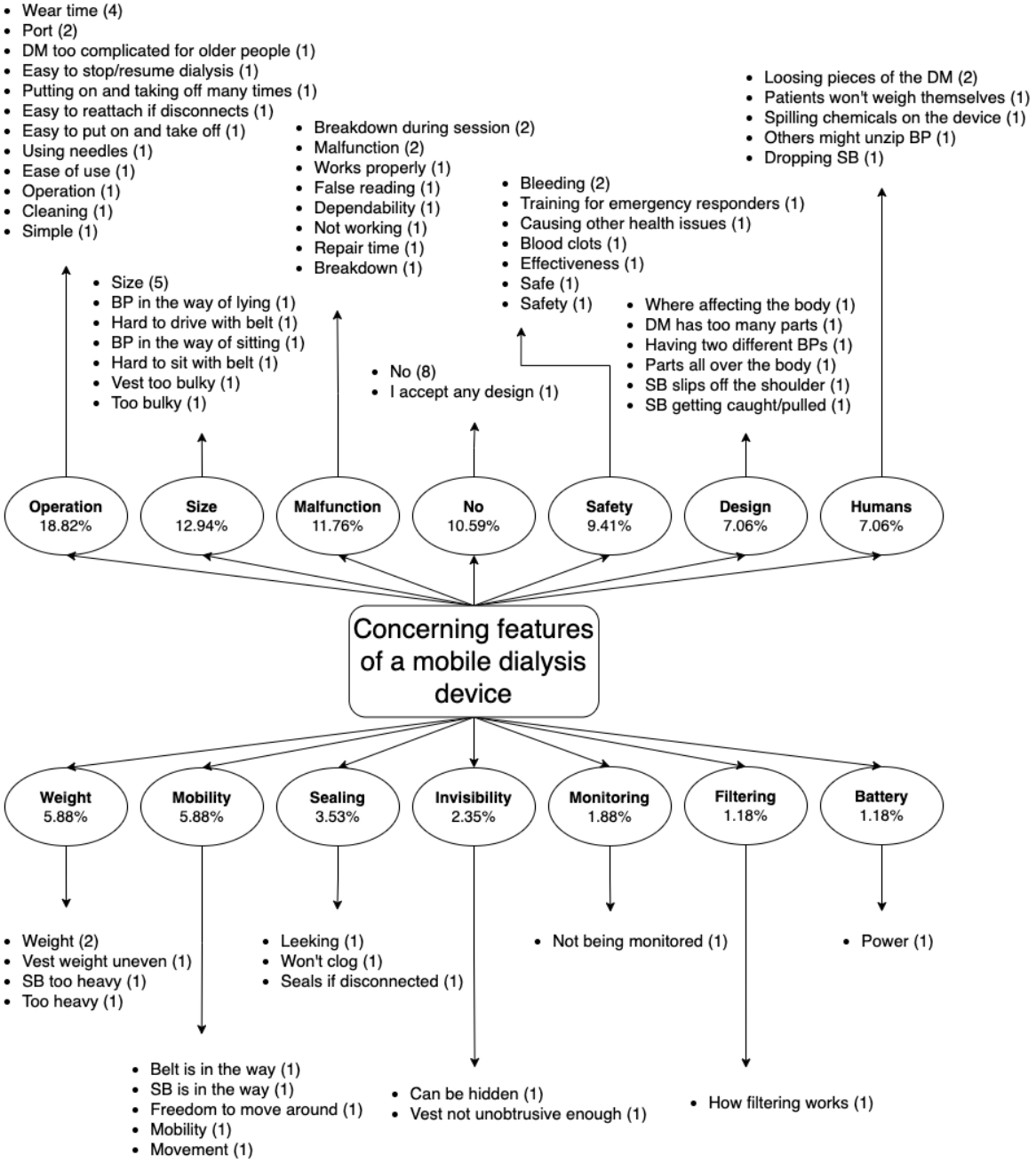

Figure 4.8: Combined keywords and comments related to patients' concerns regarding using a wearable hemodialysis device. (DM = Distributed model, BP = Back pack, SB = Shoulder bag). (Primary study population).

4.2.4 Summary and Discussion

Through the mixed approach of qualitative analysis of open-ended questions and quantitative analysis of rankings of listed items, similarities were found in the overall responses from both the patients and care partners. Majorities indicated patients' upper bodies, particularly patients' backs or the combined region of the back and abdomen, as the most ideal physical location for carrying a wearable dialysis device. Both the patients and the care partners emphasized the importance of having a small and lightweight device. At the same time, discrepancies were found when comparing the responses of the patients and care partners. For example, when asked about the preferred physical location for carrying the device, the care partners indicated preferences for carrying the device over patients' shoulder and further mentioned the arm, a location that would allow care partners to easily check on the status of the device, more frequently compared to the patients. The care partners also mentioned the waist, a location that would preclude easy monitoring, less frequently than the patients did. In describing the preferred physical location for carrying the device, the patients indicated that they preferred the belt-type design that could be hidden by clothes, while the care partners indicated that they preferred the vest design. These differences can be explained by the caregivers' two contradictory goals: the device should be designed for their patients to use both with and without their assistance as necessary.

The participants were further asked to name important features to be included in the designs of the device and subsequently rank seven device-related attributes. This approach of mixing qualitative and quantitative methods allowed for validation of which device-related attributes users most preferred and revealed additional features to be targeted in designs. The findings from the open-ended questions expand the set of important device related attributes by revealing 7 additional categories where both patients and care partners considered the operational simplicity of the device as being the most important feature. The rankings show that while the patients ranked the accuracy of the device significantly higher compared to the other attributes, both patients and care partners considered invisibility significantly less important than the other attributes.

The participants in this study were diverse in terms of their roles (i.e., patients or care partners). They also came from ethnically diverse backgrounds. In addition to considering the distinct roles of patient and care partners, participants' age was taken into account by dividing the total number of participants into 2 groups. However, no difference between the two age groups was found in terms of preferred device designs or attributes. This may be due to the study's small sample size and the fact that all of the participants were adults. Although the goal was to recruit participants using a diversity matrix that accounted for age, gender, and ethnicity to avoid response bias, the patients were all male veterans while the care partners were predominantly female. This effect is largely reflective of the existing gender imbalance in the VA population. The patients' status as male veterans may have affected the finding of invisibility being the least important feature. This finding is inconsistent with previous interview findings based on responses from non-veteran participants [109]. Instead of conducting a strictly gender-based analysis, the focus was on whether an interviewee was a patient or care partner in determining differences in design preferences and attributes. Retrieving perspectives from both patients and care partners is important as care partners are future users of the wearable dialysis device by assisting patients in need.

4.3 Users' Needs and Perspectives of a Vascular Connection Device

To help inform the early design conceptualization of a wearable hemodialysis system, this section aims to characterize patients' and care partners' perspectives of a vascular connection device. This section is comprised of four parts: First, section 4.3.1 aims to inform the initial form factors of a vascular connection device. The participants were asked to indicate the ideal physical location of a catheter and express their concerns regarding connecting the vascular connection device to a catheter, if any. The participants were also asked to indicate the largest acceptable size and heaviest acceptable weight of a vascular connection device, describe the most ideal design shape of the device, and indicate the most ideal physical location for carrying a vascular connection device. Secondly, section 4.3.2 gathers patients' and care partners' perspectives on ideal features of a vascular connection device. Thirdly, section 4.3.3 explores participants' concerns regarding using the vascular connection device, particularly in a public setting. Lastly, section 4.3.4 aims to explore fundamental

use scenarios exploring patients' and care partners' views on acceptable interaction time duration and use frequency. The results of this study may help developers of a vascular connection device identify important design aspects and perceived concerns according to users perspectives. This, in turn, may help reduce the barrier associated with connecting a hemodialysis device to a patients' blood supply.

4.3.1 Ideal Design Forms of a Vascular Connection Device

Ideal Physical Location of a Catheter

The results from an inductive content analysis of participants' responses suggested six categories of ideal physical catheter locations. The number of comments related to each category is shown in Figure **??**. Most responses suggested that the chest area (10 comments) was the ideal location, with keywords such as "chest area," "chest," and "upper torso." One participant (P6) stated, "The chest area is the most safest." Another participant noted, "The chest area looks pretty ideal to me because when you are disconnected, then it is not visible and it's not dangling off your arm or anything." The second-most mentioned ideal physical location for the catheter lines to exit was the arm (5 comments) with keywords such as "arm," "upper arm," and "left arm," followed by the abdomen (4 comments) with the keywords "abdomen" and "stomach." Other locations mentioned include an arbitrary location under clothing, the location of the lower neckline, and the location of the leg, with one comment each. The possible reasons for preferring these locations may be that these locations help disguise the device from others. For example, one participant (P29) stated, "I would say whatever the most, I guess, not noticeable, which I guess is the stomach area because I have scars down my chest, and I can't imagine having another line coming through there. I like fashion, I like to dress up and stuff. I just don't want anything that you can see." Another participant (P26) commented, "I think it should be placed on the arm. As a woman, I don't know, I just didn't like the catheter. I felt like it was just right there above my breast, and I didn't want to wear any clothing where the catheter would show. And the way a lot of women's clothing is made, there's like cleavage. So, I couldn't wear women's clothing; I had to wear my husband's shirts. [Laughs] And it also made me feel self-conscious, so I didn't want to be

intimate the whole time I had that catheter." Still another participant (P1) suggested that the design of a vascular connection device should be private, commenting, "I would imagine that something that's reachable without too much discomfort, some place that didn't come in the way of most clothing and seat belts. Or, you know, waistbands, bra straps—I would say necklines, you know, like, having it so that one could wear a relatively different range of clothing, without having to be, like, 'Oh, no, everybody can see.' Not that that matters so much, but in a place where it could be reasonably private."

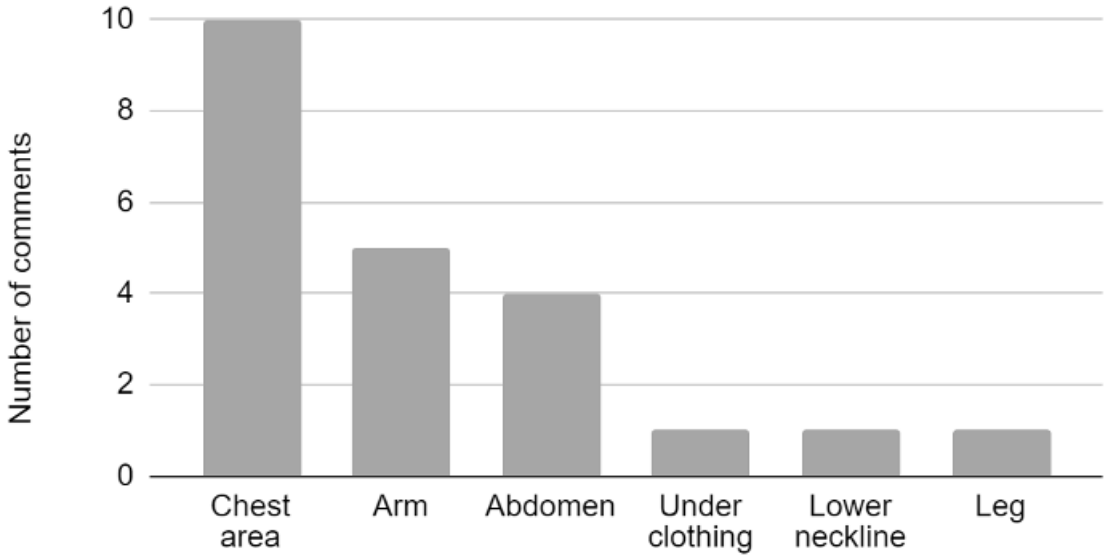

Figure 4.9: The number of comments under each identified category of ideal physical location for a catheter. Patients' and care partners' combined responses.
(Secondary study population).

Largest acceptable size of a vascular connection device

Figure 4.10 shows the number of comments related to each category of the largest acceptable size of a vascular connection device along with the accumulated percentage of participants' met expectations. Most frequently the participants mentioned size limits in reference to familiar objects such as a smartphone, a credit card, and a small bag. Some participants

responded with direct measurements such as “10 x 7 x 3 inches” or “1 x 2 inches,” which were later sorted into the categories in reference to the familiar objects mentioned. The results show that while some participants (24%) indicated their willingness to carry a small bag-sized device, more than half of the participants (62%) indicated a smartphone as the largest acceptable size for a device.

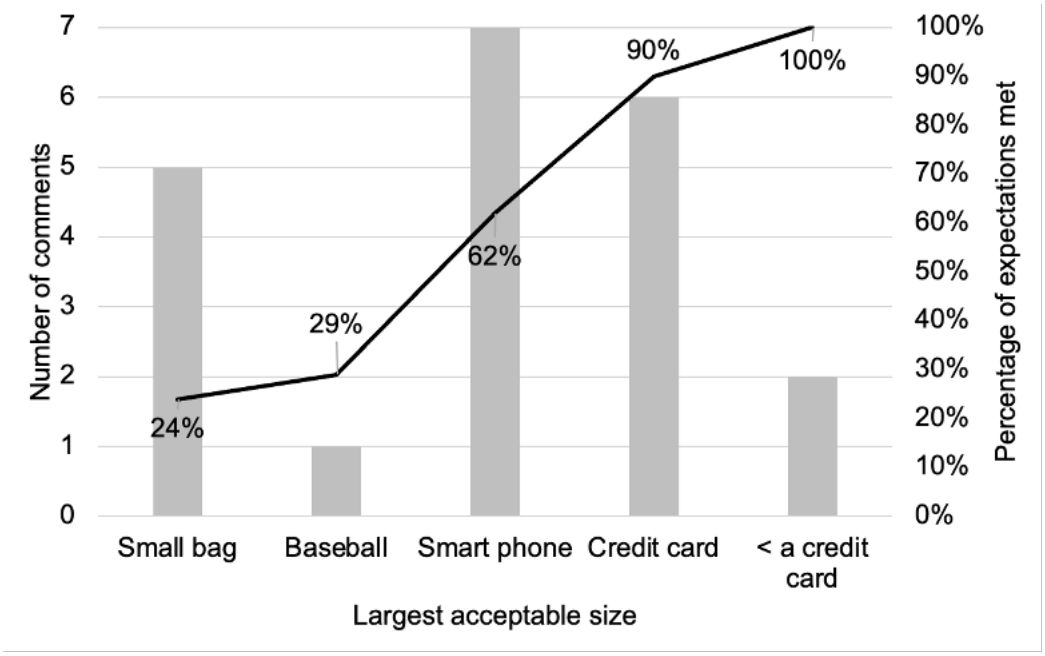

Figure 4.10: The number of comments and the cumulated percentage of expectations met regarding the largest acceptable size of a vascular connection device.
(Secondary study population).

Heaviest acceptable weight of the vascular connection device

While some participants (10%) were willing to carry a device weighing 4.5 kg, most participants (95%) indicated their willingness to carry a vascular connection device no heavier than 0.23 kg, or the weight of a smartphone device. The number of comments related to each category describing the heaviest acceptable weight of a vascular connection device along with the accumulated percentage of participants’ met expectations is shown in Figure 4.11.

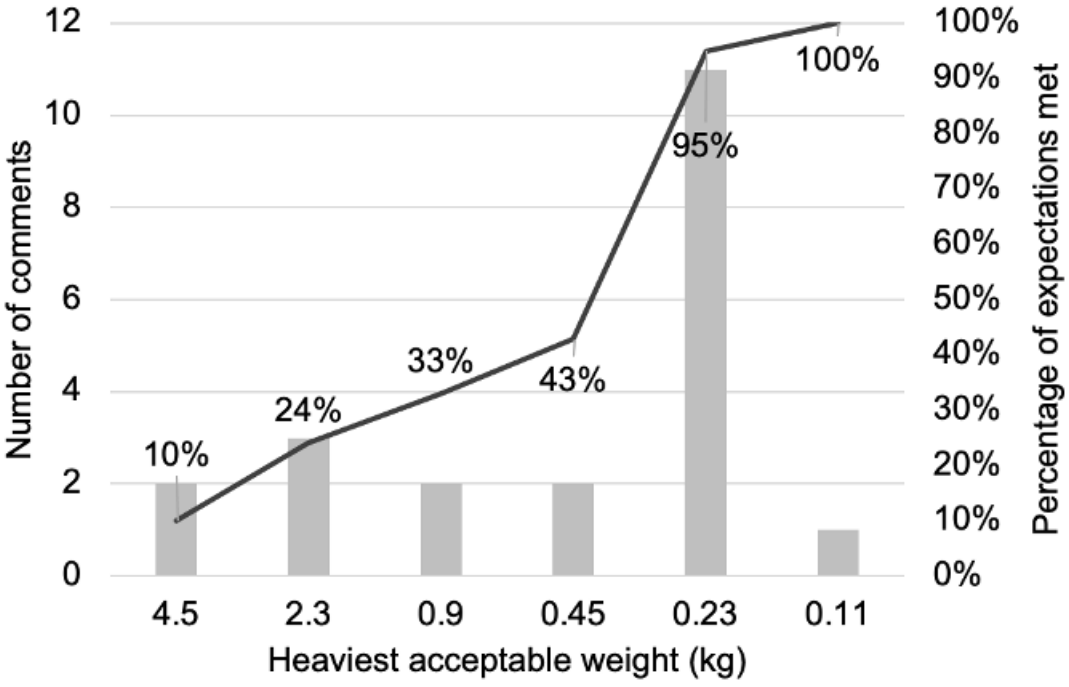

Figure 4.11: The number of comments and the cumulated percentage expectations met regarding the heaviest acceptable weight of a vascular connection device.
(Secondary study population).

The Ideal Design Shape of a Vascular Connection Device

Analyzing participants' responses for the most ideal shape of a vascular connection device the findings suggest three major shape categories: geometrical references, objects, and special features. The number of comments falling under each category of the most ideal design shape of a vascular connection device with exemplary quotations is shown in Table 4.5. In the geometrical references category, a rectangular shape was the most frequently mentioned (5 comments) followed by a square shape. Some participants referred to their most ideal shape by referencing familiar objects such as an iPhone (4 comments). In the special feature category, the participants mentioned that the most ideal shape would have rounded corners (4 comments).

Table 4.5: Identified categories of the ideal design shape of a vascular connection device along with number of comments mentioned under each category and exemplary quotations. (P = patients' identification number, CP = care partners' identification number). (Secondary study population).

Category	Number of Comments	Exemplary Quotations
Shape		
Rectangular	5	"Well, the shape probably would be rectangular, but small, like two inches by three inches or something like that." - P11
Square	4	"Well, something like that, a little square, or a little rounded at the corners, or something." - P24
Oblong or oval	2	"I guess oblong or round because not to have any rough corners that would somehow, again, while movement, having movement and bumping into something, or moving it, or jarring it. No sharp corners." - P17
Circular	3	"I kind of like round" - P25
Objects		
iPhone	4	"Cell phone. How about an Apple 11 phone?" - CP02
Small remote control	1	"I don't know, like a little remote control." - P04
Neutral purse	1	"Something neutral, you know not like a big clanking machine, but something like a purse that somebody would carry around." - P10

Table 4.5 continued from previous page

Category	Number of Comments	Exemplary Quotations
On a belt	1	"A special belt, and I would assume you would need something of that nature so it's not just hanging there open and to the air all the time but protected somewhat." - P22
Wallet	1	"Something like a wallet would be good." - P03
Deck of cards	1	"Probably like a small deck of cards." - CP16
Debit card	1	"Probably like a debit card. That would probably be good." - P28
Mug	1	"Like a mug maybe." - P29
Features		
Round corners	4	"I would say rectangular with rounded corners." - P01
Thin	2	"Well probably kind of a flatter, you know less bulky, so I would say like an iPhone, thin you know." - P09
Sleek	1	"Kind of rectangular, as sleek as possible." - CP03

The Ideal Physical Location to Carry a Vascular Connection Device

The secondary study participants were asked to rank five proposed physical locations to wear or carry a vascular connection device: in a pocket on the upper torso, around the waist or in a belt bag, in the front pocket of pants, back pocket of pants, and as a shoulder bag. A Friedman analysis was conducted and indicated that the location preferences for carrying a vascular connection device significantly differed ($\chi^2 = 12.253$, df = 4, $p < 0.05$) with a small effect size detected ($W = 0.161$). A pairwise Wilcoxon test, a non-parametric test to compare paired data, with a Bonferroni correction showed that the location of a back pocket on the pants was significantly less preferred than the locations for a pocket on the upper torso ($p = 0.038$) and the location of the waist or a belt bag ($p = 0.006$).

4.3.2 Ideal Features of a Vascular Connection Device

The findings from inductive content analysis suggests 10 categories of ideal features of a vascular connection device. Figure 4.12 shows the keywords that fell under each category. Representative quotations from patients and care partners regarding the most important features of a wearable dialysis device in Table 4.6. The analysis shows that the participants most frequently mentioned ideal features related to (1) the safety of the device, such as features promoting a safe connection to the bloodstream and features of alarms to ensure the safety of the patient (9 comments). The second-most mentioned features were related to (2) the ease of using the device, such as the ease of connection to the bloodstream and the ease of information readability (5 comments), followed by (3) features of treatment monitoring, such as an interactive and colored display of information and the recording and storing of treatment information via the internet and smartphone applications (4 comments). Other categories of ideal features of a vascular connection device include (4) special design features ensuring the safe wearing and the protection of the device, such as having a case and a cover for the device (3 comments); (5) compactness of the device, or the weight and size of the device (3 comments); (6) cleanliness, or features that reduce the risk of infection and promote easy cleaning of the device (2 comments); (7) reliability, or how reliable the device is in terms of the dialysis treatment each time (2 comments); (8) durability, or the extent of impact forces the device tolerates (2 comments); (9) independence, or patients' independent usage of the device (1 comment); and (10) portability, or easy it is to move or transport the device (1 comment).

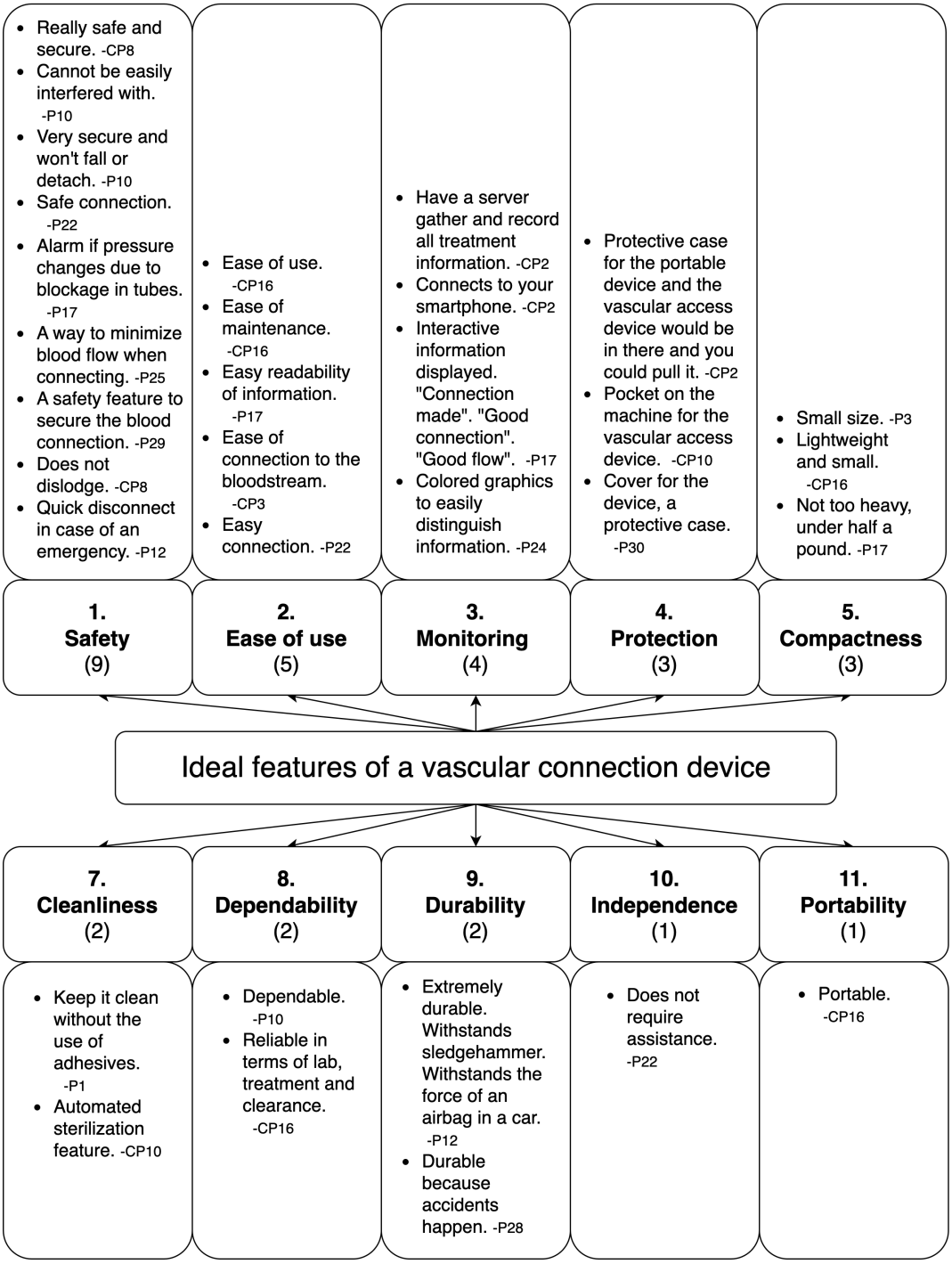

Figure 4.12: Categories of features of the ideal vascular connection device. Keywords are displayed under each category. The number in the parenthesis indicates how many times the keyword was mentioned by a participant. (Secondary study population).

Table 4.6: Identified categories of ideal features of a vascular connection device along with a category description, the number of patients indicating particular ideal feature and an exemplary quotation. (P = patients' identification number, CP = care partners' identification number). (Secondary study population).

Categories	Formulated Description	Number of Comments
Safety	Makes secure blood connections, has alarms, and allows for quick disconnections	9
Exemplary quotation	"That it would be really, really safe and secure. That it would not dislodge because then you're dealing with blood, and patients would probably faint before they could even troubleshoot the device." – CP8	
Ease of use	Is easy to operate, read, and connect to the patient's bloodstream	5
Exemplary quotation	"Well, of course, ease, being able to, you know, attach it easily." – CP3 "I like little colored graphics, though. It's easy to distinguish what you're looking at real quick." – P24	
Monitoring	Records, stores, sends, and shows treatment information with an interactive display.	4

Table 4.6 continued from previous page

Categories	Formulated Description	Number of Comments
Exemplary quotation	"If that was, like, a smartphone, you could have, like, a server, somewhere, that had all this information happening. . . . Because you could, you know, dial in to a phone number or link somewhere where it could record everything, and all that kind of stuff. And the screen of your smartphone could take the place of the screen that you're trying to have in the portable hemodialysis device." – CP2	
Design	Ensures the safe wearing and protection of the device.	3
Exemplary quotation	"Well, I would not want it to be a device that would fall off easily. In other words, I would want it to be very secure, almost like part of me that I wouldn't have to worry, 'Oh, is it going to fall off?' 'Is it going to get loose?'" – P10	
Compactness	Is small-sized and lightweight.	3
Exemplary quotation	"As long as it's a smaller size, it would be the best." – P3	
Cleanliness	Is easy to keep clean and sterile.	2

Table 4.6 continued from previous page

Categories	Formulated Description	Number of Comments
Exemplary quotation	"There has to be, of course, obviously, a way of sanitizing and sterilizing. It'd be really neat if you had a little bitty—and this complicates things—but if you disconnected it from the actual site, where the exit site for the actual catheter itself, if there was somehow a little box inside that, if you stuck it in there and pressed a button that it just automatically sterilized it or something." – CP10	
Durability	Withstands impacts of accidents.	2
Exemplary quotation	"Because of what it's doing, I want that thing to feel like I could take a sledgehammer to it. If I'm doing it in a car, okay, don't forget the force of how far or how fast a airbag comes out. I need that thing to survive basically is what I'm saying." – P12	
Reliability	Is reliable in terms of treatment, clearance, and laboratory results.	2
Exemplary quotation	"Just reliability that it works well, that it's going to give the patient a good lab, I guess, good clearance." – CP16	
Independence	Can be used independently by a patient.	1
Exemplary quotation	"Just something that's got an easy, safe connection, that I can actually get to, into myself, I can do without somebody having to help me every time." – P22	
Portability	Easy to move around.	1

Table 4.6 continued from previous page

Categories	Formulated Description	Number of Comments
Exemplary quotation	"Portable." – CP16	

4.3.3 Potential Challenges of a Vascular Connection Device

Concerns regarding Connecting a Vascular Connection Device to Catheter Lines

A total of 12 categories of participants' concerns related to connecting a vascular connection device to catheter lines were identified. Table 4.7 shows the keywords and key terms capturing patients' and care partners' concerns over connecting the vascular connection device to a patient's catheter lines. Most participants mentioned concerns with (1) infections (16 comments); followed by (2) the safety of the device and emergency situations (11 comments); (3) bleeding, blood flow, and blood clots (9 comments); (4) functioning, maintenance, and troubleshooting (7 comments); (5) ease of use and device support (6 comments); (6) privacy and body image or the catheter's influence on patients' perceived physical awareness (5 comments); (7) durability of the device (3 comments); (8) supplies needed for the device (3 comments); (9) immobility while using the device (2 comments); (10) catheter-related concerns (2 comments); (11) materials used for the device (2 comments); and (12) comfort of the patient (1 comment).

Table 4.7: Categories related to patients' and care partners' concerns regarding connecting the vascular access device to a patient's catheter lines. (P = patients' identification number, CP = care partners' identification number). (Secondary study population).

Categories	Formulated Description	Number of Comments
Infections	The risk of infections and the uncleanliness of connections from the body and back.	16
Exemplary quotation	"People might have issues with infection. Sometimes if somebody leaves in an area too long, people have had infections with like buttonholes or something like that. It can sometimes cause infection. Not in everybody, not all the time. But it might be something to kind of look out for." – CP6	
Safety and emergency	The risk of an unsafe device, without alarms, and automatic shutoff.	11
Exemplary quotation	"I want it to scream really loudly if anything's wrong. So I would like it to be loud alarm wise, if that thing's leaking in any way, and an auto shut off would be good too." – P12	
Blood flow	The risk of blood leaks, blood clots, and inadequate blood flow rate.	9
Exemplary quotation	"A blood clot or something like that. The machine had a blood clot. I could see the blood clot in the machine where it was cleaning my blood." – P4	
Malfunctioning	The risk of mechanical failure and downtime of the device.	7

Table 4.7 continued from previous page

Categories	Formulated Description	Number of Comments
Exemplary quotation	"How often does it fail mechanically?" – CP10	
Use error and lack of support	The risk of operational error and inadequate device assistance.	6
Exemplary quotation	"So, if I did something wrong, is blood gonna start spurting out of the connection on my body." – P17	
Privacy and body image	The risk of the noticeability of the device and being self-conscious.	5
Exemplary quotation	"Can I have it discreet in my purse to take it with me if I needed to? Can I hook up and hook up to the device without being noticed, I got self-conscious with it, having it attached to my stomach and when people would literally look at me. It could have been in my head, but when I saw people would look at me, but would look directly at my stomach, so they could see this line, this tube in my stomach. That was so embarrassing for me." – P29	
Durability	The risk of water damage or not withstanding temperature changes.	3
Exemplary quotation	"Like what is the limitation of heat and cold and water and things like that." – P25	
Supplies	The risk of needing too many supplies and not having enough supply storage.	3

Table 4.7 continued from previous page

Categories	Formulated Description	Number of Comments
Exemplary quotation	"Medicalization of the home is another huge barrier. And supply storage." – CP10	
Immobility	The risk of the device causing immobility to the patient.	2
Exemplary quotation	"Think about convenience, wanting to go places and going to do stuff, being spontaneous with it." – P29	
Catheter	The risk of the catheter being too long or not recommended for long-term use.	2
Exemplary quotation	"Change the recommendation of how long you can have a catheter, that's my concern. If Medicare or the dialysis, whoever the big honchos are in the sky that write the rules and the stuff for the dialysis standards and stuff like that, that's all I can say, that's the only concern that I have, period." -CP2	
Materials	The risk of being allergic or sensitive to the materials of the device.	2
Exemplary quotation	"My skin's super sensitive to the adhesive, so I'm changing the dressing, 'cause the most important thing is to keep it clean, you know, where it breaks the skin. So, coming up with some way that one could keep it clean without having to deal with – and it's almost like an impossible thing – the adhesives" – P1	
Comfort	The risk of being uncomfortable while using the device.	1

Table 4.7 continued from previous page

Categories	Formulated Description	Number of Comments
Exemplary quotation	"Well, if it's physically on the body, that it's comfortable." – P17	

Concerns regarding Connecting Catheter Lines to a Vascular Connection Device in Public Settings

Inductive analysis of participants' concerns regarding connecting the catheter lines to a vascular connection device in a public setting suggests seven categories of concerns. Categories of participants' concerns regarding making the blood connection in a public setting, category description, the number of comments under each category, and exemplary category quotations are shown in Table 4.8. The categories of participants' concerns are as follows: (1) infection risk, or participants who are concerned with the atmosphere being sterile so as to avoid infections (7 comments); (2) no concerns, or participants who have no concerns over making the connection in a public setting (6 comments); (3-5) privacy, or participants who are concerned over how noticeable the act of making the bloodstream connection would be or how much of their bare body they would be showing (3 comments); (3-5) stigmatization, or participants who are concerned over the perceptions of other people (3 comments); (3-5) not in public, or participants who do not want to make the connection in public but indicated no specific reasoning (3 comments); (6) only in an emergency, or individuals who are willing to make the connection but only in emergency situations (2 comments); and (7) lack of trust, or individuals who are concerned about the delicate designs of the device and the resulting complications (1 comment).

Table 4.8: Identified categories of participants' concerns regarding making the blood connection in public. Category description is provided along with the number of participants and an exemplary quotation. (P = patients' identification number, CP = care partners' identification number). (Secondary study population).

Categories	Formulated Description	Number of Comments
Infection risk	The risk of infection in an unsterile environment	7
Exemplary quotation	"Just the atmosphere I'm in. Is it a clean, sterile atmosphere? Like when I did peritoneal, I had to be in a room when I did my hooking up, that was not a lot of people, and it was somewhat sterile." - P22	
No concerns	-	6
Exemplary quotation	"Not really. You know it's, to me it's a lot like turning on a radio or using a cell phone or something. I mean I don't see it as something I might be embarrassed about." - P10+D4:D9	
Privacy	The risk of the device being noticed by others and the risk of being self-conscious	3
Exemplary quotation	"Well of course that depends on you know how obvious it would be and how much of your bare body you would be showing." - CP03	
Stigmatization	The fear of other people's perceptions	3
Exemplary quotation	"I wouldn't want to do it in public just because of [...] the perception of it from other people. If they see me, I don't like that, so I, myself, would not do it in public." - P29	

Table 4.8 continued from previous page

Categories	Formulated Description	Number of Comments
Not in public	Unwillingness to make the connection in a public setting	3
Exemplary quotation	"No, I wouldn't wanna do that, I don't think." - P18	
Only in an emergency	Unwillingness to make the connection in a public setting on a routine basis	2
Exemplary quotation	"I don't think he would be comfortable doing probably any of it in public. I mean if it were an emergency he certainly would." -CP03	
Lack of trust	Accidents caused by delicate designs and other factors	1
Exemplary quotation	"Somebody bumping into me and tangling up the cord and disconnecting it on accident." - P12	

4.3.4 Users' Primary Acceptance of Time Spent in Device Interactions

Longest Acceptable Time Spent in Making the Blood Connection

Figure 4.13 shows the number of comments under each of the time durations mentioned by the participants as the longest acceptable along with the accumulated percentage of participants' met expectations. The inductive content analysis, which involved gathering participants' responses and sorting them into bins of the time duration mentioned, showed that while more than half of the participants (58%) were willing to accept a time duration of 5 minutes, the vast majority of participants (90%) were willing to accept a time duration of no longer than 3 minutes.

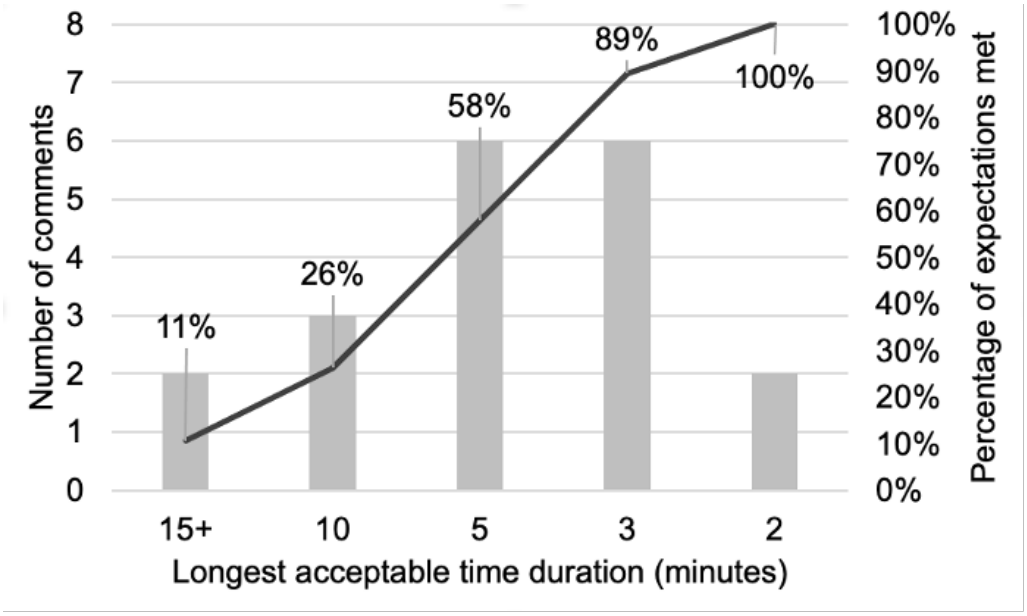

Figure 4.13: The number of comments and the accumulated percentage of expectations met regarding the longest acceptable time duration for making the blood connection using a vascular connection device. (Secondary study population).

Acceptable Number of Daily Vascular Connections

Figure 4.14 shows the number of comments under each number of daily blood connections using a vascular connection device along with the accumulated percentage of participants' met expectations. The inductive content analysis showed that while 13% of the participants were willing to make the blood connection four times a day, more than half of the participants (63%) were only willing to make the connection twice a day.

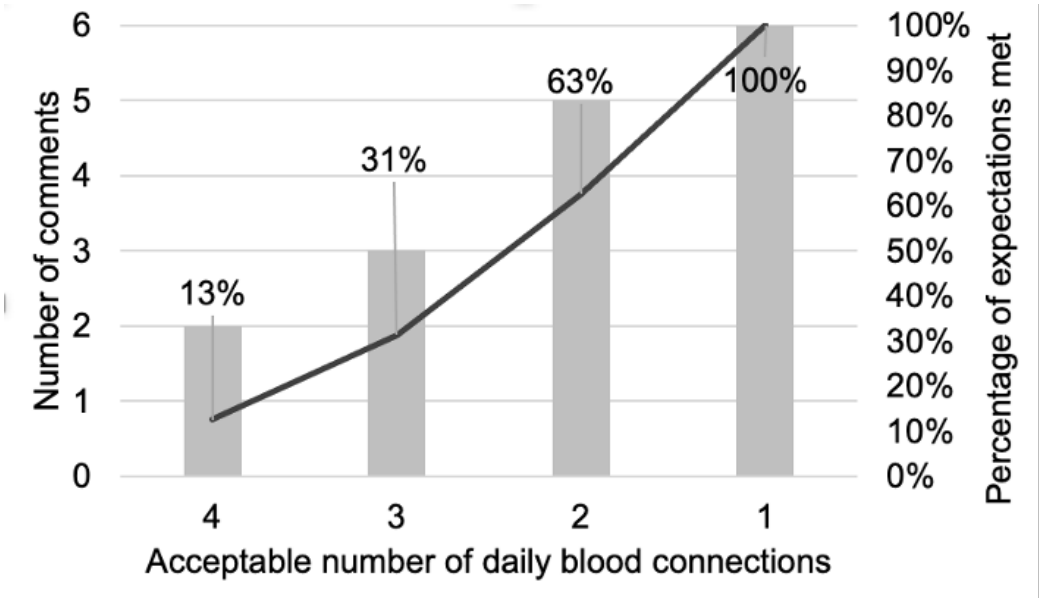

Figure 4.14: The number of comments and the accumulated percentage of expectations met regarding the acceptable number of daily blood connections. (Secondary study population).

4.3.5 Summary and Discussion

This section aims to help inform the early design conceptualization of a needleless vascular connection device by characterizing patients' and care partners' perspectives through both quantitative parameters and qualitative findings. The goal of this section is both theoretically grounded by the fact that the starting point of any design process begins with identifying unmet needs [157] and empirically grounded by the previous finding that ESRD patients and care partners want a needleless and user-friendly way to access the patients' blood supply for wearable hemodialysis treatments [97]. This section fills a gap in the literature by characterizing the early design concepts of a vascular connection device based on users' perspectives.

The wide range of design parameters identified in this section may be helpful when multiple versions of prototypes and final products are considered. The design parameters in this section include the preferred location of a catheter as a patient's chest area, followed by the arm and abdomen (Figure 4.9), and the preferred physical location for carrying a vascular

connection device as the locations for a pocket on the upper torso or the location of the waist or as in a belt bag (section 4.3.1). The findings also include ideal form factors such as the largest acceptable size (Figure 4.10), heaviest acceptable weight (Figure 4.11), and shape (Table 4.5). It is worth noting that the form factors in this section reflect a range of participants' responses instead of single parameters, assuming that the ESRD patients and care partners in this study are representative of the diverse user population of the future vascular connection device. As a vascular connection device is currently in the initial design stages, it is not surprising that participants' specifications vary due to their visions of the most ideal device. If some design specifications during the next phase of design fabrication do not meet users' needs, or if more than one version of the device prototypes are developed, the range of design parameters identified in this section will be beneficial when considering second- or third-preferred design alternatives. Given that the human-centered design process is an iterative process of embedding users' perspectives throughout the entire product development cycle [219], patients' and care partners' perspectives should also be gathered in the next product development cycle, especially after low- or high-fidelity prototypes have been developed. The findings in this section regarding the hypothetical design of the a vascular connection device will help guide design transitions in the development of vascular connection device prototypes.

The findings of the current study will also enable researchers to develop use-case scenarios to be considered in the next evaluation phase of device development. Responses indicating that most participants are willing to spend three to five minutes once or twice per day in making the blood connection (Figures 4.13 and 4.14), as well as responses related to potential usage barriers (Tables 4.7 and 4.8) and ideal features of the device (Table 4.6), make it possible to construct multiple versions of use-case scenarios. Such diversified scenarios are especially useful in the planning stages of a vascular connection device, as they help stakeholders and developers understand the usage of a vascular connection device from users points of view. Ultimately, the future patient-centered vascular connection device developed by uncovering users' perspectives has the potential to reduce failure rates [133, 167] while at the same time optimizing resources [133]. Such protocols are directly in line with human factors engineering principles that consider human capabilities, limitations, and

characteristics when designing tools, devices, and systems [71].

The exploration of the most ideal catheter location (Figure 4.9) attests to the importance of ensuring patients' medical privacy. Although most participants indicated that they would prefer to have the catheter located on the chest, risking exposure of the patients' illness, particularly for women, other mentioned locations may help ensure the discreetness of the patient's illness such as the location of the abdomen. These findings are corroborated by the exploration of participants' concerns about connecting the catheter to a vascular connection device (Table 4.7), particularly in a public setting (Table 4.8). The participants reported fearing that others would notice the device or that they would be stigmatized for using the device. These findings highlight the importance of ensuring the vascular connection device can be hidden and concealed from the outside, which is in line with previous finding showing invisibilty is one of patients' frequently mentioned attributes in designing a mobile hemodialysis device [109].

The limitations of the current study can be used to guide future research directions. Firstly, although the goal was to recruit a diverse group of dialysis patients and care partners following a diversity recruitment matrix that took into consideration age, gender, and race, the sample of 23 participants limited the ability to quantify the effect of demographic factors on vascular connection designs. Furthermore, the demographics of hemodialysis patients have changed over the past 10 years, with increased numbers of elderly and pediatric patients [54, 141, 201]. Demographic factors have been found to affect patients' and care partners' vascular access preferences and outcomes [224]. Future research should consider such demographic diversity when predicting factors that may influence vascular connection preferences by recruiting a larger and more demographically diverse sample of study participants. Secondly, due to the hypothetical nature of the questions along with limited design information, some participants may have experienced difficulties expressing their needs and preferences for a vascular connection device. This may also be due to individual differences in communication style and patients' health conditions linked to potential interview fatigue. Likewise, given the limited information regarding the designs of a vascular connection device, some of the participants' answers might have been influenced by their current vascular access experiences. For example, when the participants were asked how many times per

day they would be willing to connect and disconnect to a vascular connection device for mobile hemodialysis treatments, the findings show that most participants were only willing to connect and disconnect once per day (Figure 4.14), reflecting their current treatment schedules. Lastly, the current design of the vascular connection device is based on a catheter option only. Other types of vascular access were excluded from consideration because they require needle insertion. Evaluating multiple prototypes that offer diverse vascular connection options should be considered. It is worth noting that to date, no studies have considered patients' and care partners' perspectives on the design of a vascular connection device. This section can provide designers and manufacturers with timely information that may help guide preliminary decisions about how to create an end product that will ultimately achieve clinical and commercial success.

Chapter 5

PATIENTS' AND CARE PARTNERS' NEEDS AND PERSPECTIVES OF MONITORING AND TRAINING PROCEDURES FOR WEARABLE HEMODIALYSIS TREATMENTS

The goal of this chapter is to answer research question R2 by characterizing the design requirements for monitoring and training procedures for a wearable hemodialysis device.

First, to characterize the design requirements of a wearable hemodialysis monitoring system that helps support patients' self-management and symptom-monitoring behaviors, this study explored patients' and care partners' awareness of symptoms of ESRD before and after a patient receives dialysis therapy. The participants were asked to reflect on current and prior dialysis procedures and asked about indicators suggesting patients' need for dialysis treatment. They were also asked if they noticed any indicators suggesting a successful removal of excess water, solutes, and toxins from the patients' bloodstream (section 5.1). Then, patients' and care partners' expectations for wearable hemodialysis monitoring and training procedures were explored (sections 5.2 and 5.3). The results from this chapter may help guide the designs of a monitoring system and training procedures to help support patients' self-management and symptom-monitoring behaviors.

5.1 Users' Awareness of Disease Symptoms Before and After Dialysis Treatment

5.1.1 Indicators of ESRD Suggesting Patients' Need for a Dialysis Treatment

Figure 5.1 displays the categories and keywords related to patients' and care partners' awareness of indicators of ESRD suggesting a patient's need for dialysis treatment. Most participants mentioned that they knew the treatment was needed based on the scheduled sessions mentioned by a health care provider (20 out of 54 comments). Although some participants specifically stated that they did not recognize or did not have any physical indicators suggesting the need for treatment (5 comments), other participants reported diverse physical

signs indicating the need for treatment. Participants reported that they knew the treatment was needed based on fluid retention or swelling (8 comments); oral changes such as slurred speech and foul-smelling breath (5 comments); fatigue (5 comments); a specific feeling indicating patients' deteriorating health (3 comments); complexion (2 comments); breathing difficulties (2 comments); itching (1 comment); cramping (1 comment); shaking (1 comment); and lack of sleep (1 comment). One care partner from Seattle stated, *"Sometimes at night he gets out of breath. He can't breathe too well. And that means that he's gathered too much fluid in his body. And sometimes we are up practically all night. Just sit up and once I had to get in the middle of the night and bring him to the emergency room."* A patient from Nashville reported, *"Other than being on a schedule, you can feel it when you have too much fluid on you or when you've eaten incorrectly and you need to cleanse yourself, and that can be signs of itching. It could be cramping. You can also feel your [waste] build go up if you've eaten too much protein. So your body gives you signs that tell you it's time for another session."*

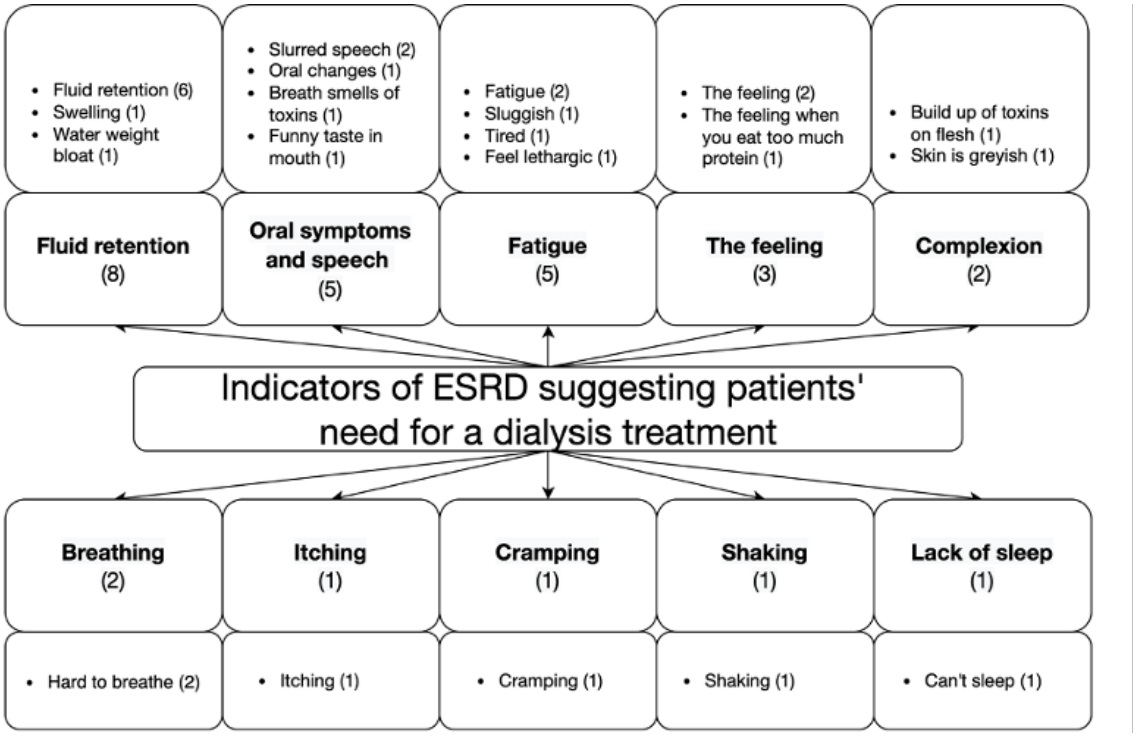

Figure 5.1: Categories and keywords related to patients' and care partners' awareness of indicators of ESRD suggesting patients' need for dialysis treatment. The number in parentheses next to each category indicates the number of times a related keyword or comment was mentioned by a participant. (Primary study population).

5.1.2 Indicators of ESRD Suggesting a Successful Dialysis Treatment

Categories and keywords related to patients' and care partners' awareness of indicators of ESRD suggesting a successful dialysis treatment are shown in Figure 5.2. Although four participants were unable to identify any indicators (4 comments), most of the participants reported observing physical or emotional changes (40 comments). Increased energy was the most frequently observed indicator. One patient from Louisville stated, *"Oh, I feel great. I've got re-energized, a little bit. To me, it is normal now. When I first started, I felt a little funny, but now it's normal to feel the way I feel, and I don't gotta worry about all the toxicity that is in my bloodstream. I know it's been cleaned out."* Other comments related to indicators of a successful treatment included a feeling of wellness (7 comments), reduced

fluids or weight loss (5 comments), increased productivity (5 comments), positivity (4 comments), clear eyes (2 comments), improved complexion (2 comments), a lack of physical pain or cramping (2 comments), improved breathing (2 comments), and better-smelling breath (1 comment). Participants who did not report any physical or emotional signs of successful dialysis treatment instead mostly reported objective measures (9 comments), including parameters displayed on currently used dialysis machines, patients' weights before and after treatment, and results from regular laboratory tests. One Nashville patient stated, *"It's always performed well because that's what the machine is supposed to do."* Another patient from Nashville stated, *"If I go and weigh, I know if they have pulled correctly or not. Sometimes the machine pulls more than we expect, and at that time they have to pull me back and give me some—what do you call it, saline?"*

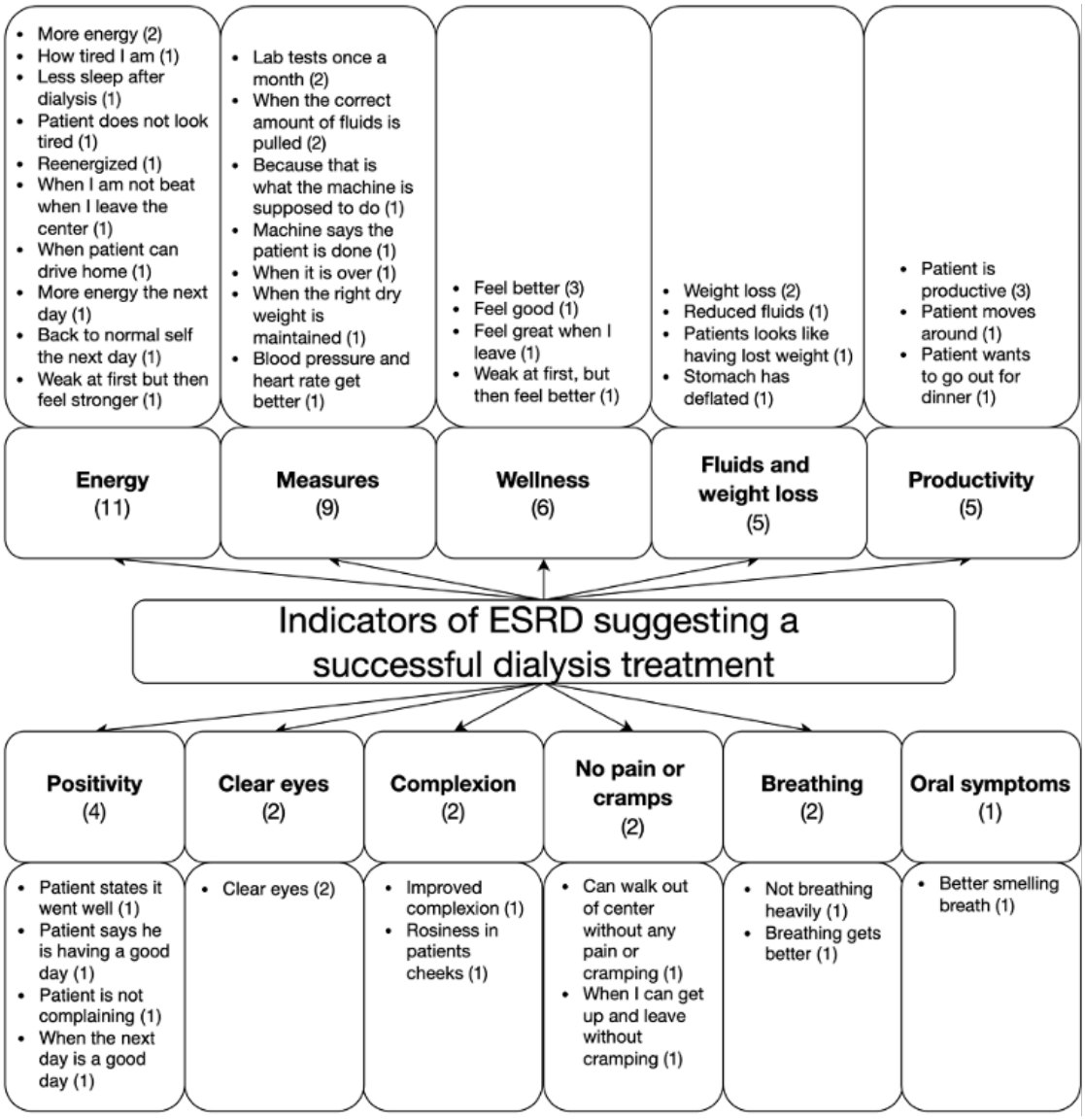

Figure 5.2: Categories and keywords related to patients' and care partners' awareness of indicators of ESRD suggesting a successful dialysis treatment. The number in parentheses next to each category indicates the number of times a related keyword or comment was mentioned by a participant. (Primary study population).

5.2 Expectations for Wearable Dialysis Monitoring Procedures

A total of 28 comments related to patients' and care partners' design expectations for mobile hemodialysis monitoring were identified. As shown in the first and second categories in Table 5.1, general features of treatment monitoring were most frequently mentioned (9 comments). Participants also frequently mentioned the need for establishing a monitoring procedure that would take the form of regular follow-up sessions with the patients by a healthcare worker (5 comments). The participants further mentioned the need for a system that monitors patients' heart condition and blood pressure (5 comments), includes an alarm that notifies patients of urgent medical, or equipment needs (3 comments), allows another person to monitor the patients during and after dialyzing (3 comments), and uses mobile phones or watches to automatically record and send patients' information to the dialysis center (3 comments) Overall, participants wanted a mobile hemodialysis device with an interface that would display indicators of patients' health conditions, such as the current and remaining status of their dialysis treatments, blood pressure, and heart rate, while the patients were connected to the device. Some participants wanted to be able to access these recordings via smart applications that would ideally send these recordings to a dialysis center for remote monitoring of patients' health conditions. The participants emphasized the need for a regular follow-up procedure to ensure patients' successful self-management of their mobile hemodialysis treatments.

Table 5.1: Identified categories of design features of a wearable hemodialysis monitoring system. A category description is provided along with exemplary quotations from patients and care partners related to mobile hemodialysis monitoring. The number in parentheses indicates the number of comments under each category. (Primary study population).

Categories	Formulated Description	Number of Comments
Treatment monitoring	Features that monitor and display treatment parameters.	9

Table 5.1 continued from previous page

Categories	Formulated Description	Number of Comments
Exemplary quotation	"Something where the patient can see the level of the dialysis." (Louisville care partner)	
Regular follow-up care	Regular communication sessions where the patients report their experiences and receive in return guidance and support.	5
Exemplary quotation	"I would like for my patient partner to be able to use a mobile device. If it's well monitored, and there is follow-up with the machine and with my patient partner and seeing what his feelings are about wearing it and how things are going in the home. I think that would be great." (Puget Sound care partner)	
Monitoring of vital signs	Features that monitor patients' vital signs including heart rate and blood pressure.	5
Exemplary quotation	"The most important feature to me would be something that monitors the blood pressure while he's receiving his dialysis because that's what we have a problem with. His blood pressure always drops. So that would be the most important thing to me if they could put something like that on that mobile device." (Louisville care partner) "Most important feature would be monitoring the heart." (Puget Sound patient)	
Secondary monitoring	Partnership in care to ensure patients' safety.	3

Table 5.1 continued from previous page

Categories	Formulated Description	Number of Comments
Exemplary quotation	"Having a second person to monitor you while you're going through it in case you would have a seizure, or something wasn't working right." (Nashville patient)	
Safety monitoring	Features ensuring the safety of the patient: alarms for urgent medical of equipment need.	3
Exemplary quotation	"I think the device should have an alarm that will tell the patient when there's an urgent medical need or equipment need. I think the device should also have a feature that the patient can touch a button or something to call the VA dialysis unit directly if there is a problem or if they have a question." (Puget Sound care partner)	
Smart and remote monitoring	Connects to smart devices where treatment information can be accessed and automatically transmitted to the patients' health care team.	3
Exemplary quotation	"I think for the monitoring part, you know, it could be built into it...it would be Bluetooth—so that, actually, the mobile device could be used to show all the readings. And then it's all recorded anyway. And that could actually be transmitted to wherever it needed to be to—because I'm sure that they would want to have someone monitored—or to use somewhere. You know, a center. That way, they could actually see the, you know...what's going on with each patient. And it would be automatic." (Puget Sound patient)	

5.3 Expectations for Wearable Dialysis Training Procedures

The results of the inductive content analysis indicated 11 categories of patients' and care partners' expected training before using a mobile hemodialysis device.

Key sentences under each category are shown in Figure 5.3. Participants most often indicated that they expected to receive training on how to operate the device (26 comments), particularly in terms of operational procedures such as how to clean the device between dialysis treatments, how to charge the device, and how to read the device without a user manual. Some participants expressed their training expectations without mentioning any specific features or usage scenarios (16 comments). One patient and one care partner, both from Puget Sound, expected the training to be "very careful and complete, so I know exactly what to do at any given situation" and "like a nursing school. To go in and to learn all the stuff, to understand the equipment. I'm not a techy person and that would scare me that I would, you know, to be able to understand that and to be able to process it."

Participants also indicated that they expected the training to include information on the functionality of the device. They expected to learn how the device itself performs the dialysis procedure (13 comments), how to prevent errors, how to recognize problems and recover from malfunctioning (9 comments), how to connect the device to the patient's bloodstream (7 comments), and how to handle emergencies, especially cases of heart failure or low blood pressure (7 comments). The patients and care partners expected to receive in-person, hands-on training during which they could physically interact with the device under guided instruction and observe other patients using the device (5 comments). They also expected examples of device usage such as how long patients are expected to use the device, how to carry out their daily activities while using the device, knowing for which activities it is safe and applicable to use the device (4 comments), as well as training evaluations by a health care worker to determine if the patient is capable of operating the device (4 comments). Other training expectations included information about the physiology of the human body concerning kidney failure and self-care health management.

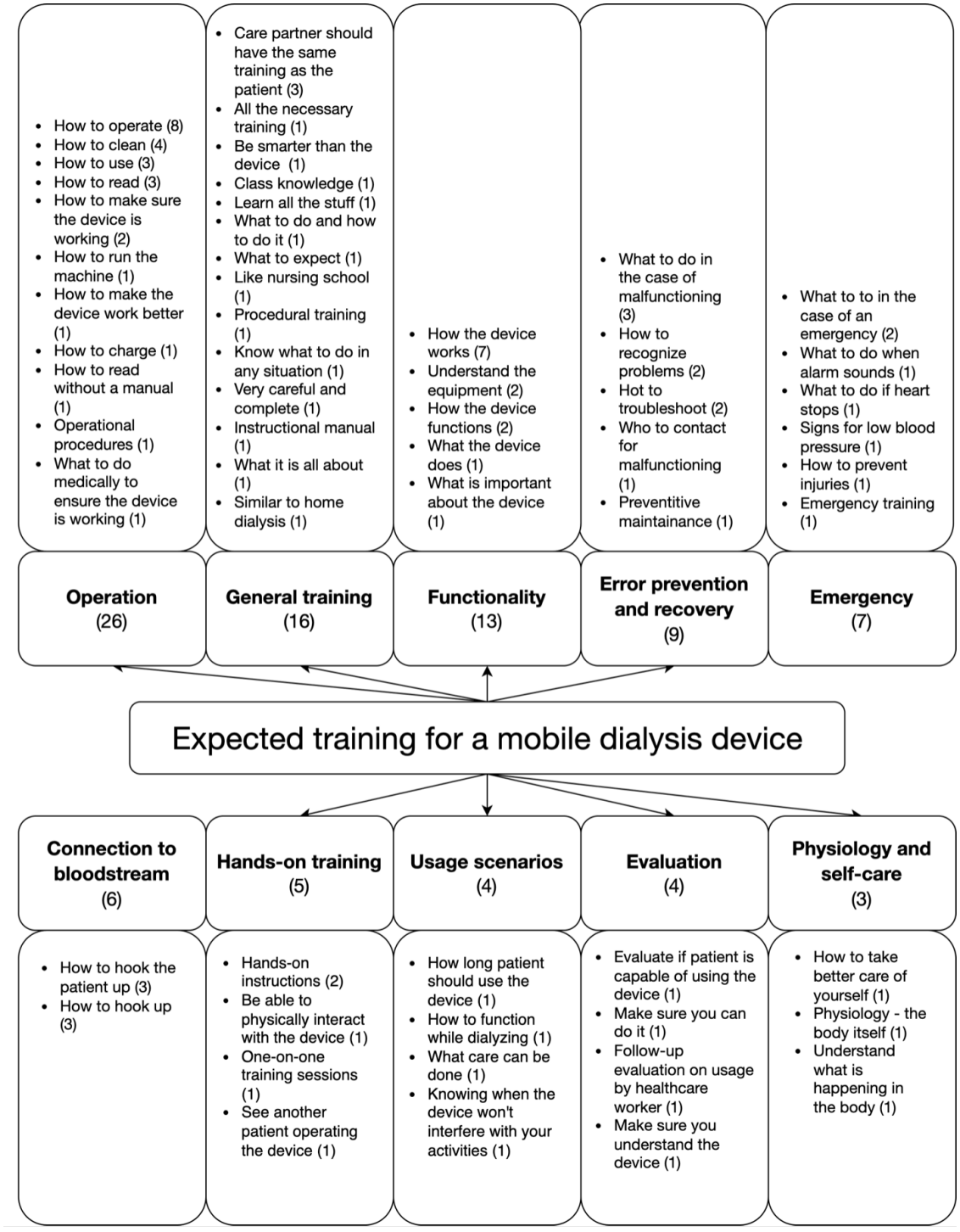

Figure 5.3: Categories formed with keywords or short phrases related to the training that patients and care partners expected to receive before using a mobile dialysis device. The number in parentheses next to each category indicates the number of times a related keyword or comment was mentioned by a participant. (Primary study population).

5.4 Summary and Discussion

To the best of my knowledge, this section is the first to characterize the design requirements for monitoring procedures for a wearable hemodialysis device using a human factor engineering approach. To help support patients' self-monitoring behaviors, I explored patients' and care partners' awareness of ESRD symptoms that suggest a patient's need for hemodialysis treatment as well as indicators that might suggest a hemodialysis treatment has been successful. I also explored patients' and care partners' design expectations regarding ideal monitoring procedures before patients and care partners begin using a mobile hemodialysis device.

In exploring patients' and care partners' awareness of indicators that suggest a patient's need for dialysis treatment, I found that patients and care partners notice physical and emotional changes in patients before and after they receive dialysis treatment. While some participants reported actively noticing patients' physical or emotional changes (e.g., slurred speech, fluid retention, and fatigue), most of the participants indicated passively knowing from the patients' prescribed treatment schedules when treatments are necessary (Figure 5.1). In contrast, while few patients referred to objective measures (e.g., patients' weight, blood pressure, treatment duration) when asked about their awareness of indicators of successful dialysis treatment, most of the participants reported a range of physical, emotional, and cognitive changes in the patients (e.g., increased energy, weight loss, wellness, positivity, and productivity) as indicators of successful dialysis treatment (Figure 5.2). The physiological indicators identified in this section may help maintain patients' confidence in the self-management of their dialysis therapies [96]. Studies show that monitoring target parameters can help support patients' self-management behaviors, ultimately facilitating the patients' well-being [230]. Additionally, successful self-management of one's health is dependent on good communication between a patient and clinician where a patient is able to report their disease indicators and experiences and receive in return information, support, and guidance [37]. These findings have the potential to guide researchers in designing a interface for a wearable hemodialysis device that incorporates the monitoring of patients' physiological, emotional, and cognitive changes during their treatments and helps facilitate

communication between a dialysis patient and the patient's healthcare team.

Analyzing patients' expectations for wearable dialysis monitoring procedures, I uncovered that patients and care partners would like device-integrated monitoring features that automatically track patients' health and treatment-related factors (e.g., heart rate, blood pressure, and levels of dialysis). The patients also expected smart and remote monitoring options that allow for digital and wireless access to patients' treatment records, thereby extending the interactive communication between dialysis patients and the patients' healthcare teams. In addition, the participants indicated they would like the ability to track and capture individual target parameters with notifications to both parties when a parameter falls outside of pre-specified ranges. Incorporating the monitoring features identified in this section (Table 5.1) into the designs of wearable hemodialysis devices has the potential to improve patients' mobile hemodialysis experiences while simultaneously yielding better clinical outcomes and reducing treatment costs. Remote monitoring of patients' physiological indicators and mobile hemodialysis treatment data such as patients' vital signs, treatment adherence, and ultrafiltration values may help reduce the risk of repeated or unnecessary hospitalizations [53, 135, 190].

Despite the goal of supporting ESRD patients' independent management of their dialysis therapies, the findings strongly suggest that many patients long for partnership in care via bidirectional monitoring between the patient and the patient's provider. Bi-directional monitoring would allow a patient to self-manage their therapies while simultaneously being under safety supervision and support. Remote safety supervision and support entails the recording and sharing of patients' individual health information across geographically diverse regions and allows healthcare workers to access both longitudinal and near-instantaneous recordings of patients' physiological and treatment measures. Remote supervision through monitoring allows healthcare workers to identify instances of urgent medical and equipment needs or longitudinal trends suggesting patients' need for additional education or support. Such remote patient monitoring has the potential to help facilitate medical decision-making and support patients in self-managing their dialysis therapies outside of medical centers [153, 115, 139, 218]. To the best of my knowledge, the expectation has been partially resolved through a health information-sharing platform that is currently available on the

market [5]. Although the current health information sharing platform shows potential in supporting patients' successful dialysis by incorporating it into the mobile hemodialysis system, the platform mainly focuses on in-center treatments and aims to support clinicians' workflow more than patients' self-management of mobile treatments. To better support dialysis across different user groups and locations, these findings can be integrated into data management platforms for both current and future dialysis devices. Such integration that is tailored according to users' needs and expectations may strengthen the link between a dialysis community and information technology that in return helps support patients' successful dialysis experiences.

Chapter 6

CLINICIANS' PERSPECTIVES OF A WEARABLE HEMODIALYSIS SYSTEM

Recognizing the important role of doctors and nurses in the early stages of medical device design, the objective of this chapter is to answer research question R3 by gaining insight into clinicians' perspectives on a wearable hemodialysis device. With their experiences and proximity to patients' medical needs, nephrologists and nephrology nurses offer unique perspectives that can inform the design and implementation of new hemodialysis devices.

First, to gain insight into clinicians' views on different treatment modalities and patients' choice of treatment, clinicians' views were gathered on in-center, home-based, and mobile hemodialysis treatments (sections 6.1.1 and 6.2.1). Then, clinicians' perspectives of potential benefits (sections 6.1.2, 6.2.2), potential barriers to recommendation (sections 6.1.3 and 6.2.3), and ideal features of a wearable hemodialysis device were explored (sections 6.1.4 and 6.2.4). Lastly, to gain insight into clinicians' perspectives of proposed devise designs, clinicians' preferred design type of a wearable hemodialysis device was explored (sections 6.1.5 and 6.2.5).

6.1 Nephrology Nurses' Perspectives for the Designs of a Wearable Dialysis Device

6.1.1 Nephrology Nurses' Perspectives towards Dialysis Modalities and Patients' Choice of Treatment

The perspectives of nephrology nurses toward dialysis modalities are summarized in Figure 6.1. Although there is general agreement that home-based dialysis can improve quality of life and clinical outcomes, perceptions on how to accomplish these goals vary. Collectively, the participants either strongly agreed or agreed that home-based dialysis treatments offer ESRD patients greater quality of life (100% of participants) and improved clinical outcomes (97%

of participants) compared to in-center dialysis treatments. The participants (100%) also strongly agreed or agreed that increased frequency of dialysis may improve patients' clinical outcomes and that a portable hemodialysis device or a wearable hemodialysis device has the potential to improve patient's quality of life by allowing them to travel and dialyze at their preferred time and location (97% of participants) or undergo continuous dialysis treatments (94% of participants), respectively. The participants (100%) also strongly agreed or agreed that with appropriate training, patients can learn to safely connect and disconnect a dialysis device to their catheter for blood access. Exploring nephrology nurses' views of patients' choices and nurses' confidence in recommending different modalities of treatment, most participants (53%) either strongly agreed or agreed that they would feel more comfortable recommending dialysis treatments outside of centers if they had a way to easily monitor the patient's health status and treatment. Most participants (84%) either strongly agreed or agreed that they try their best to persuade patients to choose a modality of treatment that offers them the greatest quality of life and best clinical outcomes even though the patients may be nervous about trying it. In addition, most participants (69%) either strongly disagreed or disagreed that they don't recommend home-based dialysis unless the patient has a care partner. Half of the participants (50%) either strongly agreed or agreed that all patients are given the same opportunity to choose their preferred modality of treatment while the other half (47%) tended to disagree or strongly disagree. Similarly, some participants (53%) also either strongly agreed or agreed that there are limited choices for patients in choosing a modality of treatment, and most participants (63%) either strongly agreed or agreed that current treatments are one-size-fits-all and should be more individualized.

Analyzing nurses' views of in-center dialysis treatments being preferred as they give the patient the comfort of having a clinician oversee their treatment our findings show mixed responses where some participants (34%) either strongly agreed or agreed, a slight majority of participants (38%) neither agreed nor disagreed and some participants (28%) either disagreed or strongly disagreed. Most participants (44%) strongly disagreed or disagreed that training programs for home-based dialysis are poorly developed, and most participants (43%) strongly disagreed or disagreed that current home-based dialysis devices are too complicated to use.

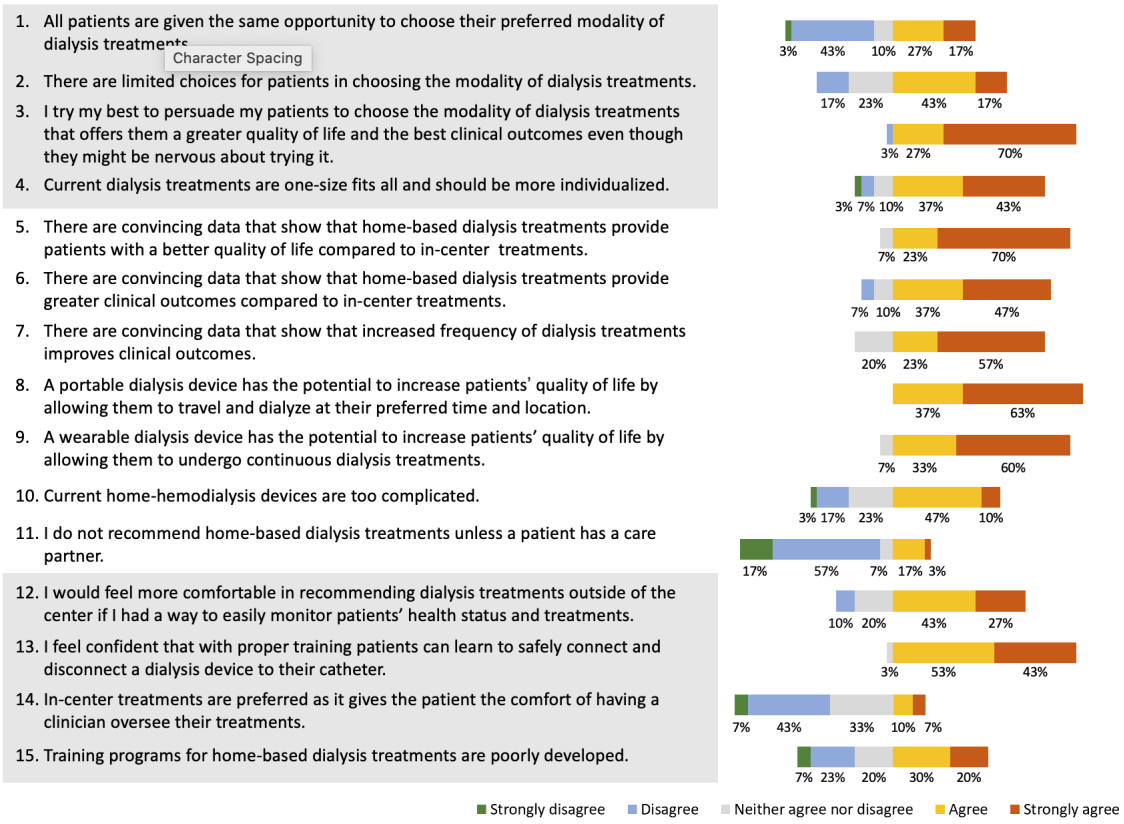

Figure 6.1: Nephrology nurses' perspectives towards dialysis modalities, home-based dialysis programs, treatment modification, and portable and wearable dialysis devices.

6.1.2 Benefits for Patients Afforded by a Wearable Dialysis Device

Inductive content analysis of participants' responses suggested four categories of benefits a wearable dialysis device could offer a dialysis patient. Table 6.1 shows the identified categories and sub-categories of the potential benefits a wearable hemodialysis device can offer a patient along with the formulated description of each category.

Most frequently the participants talked about how a wearable hemodialysis device can benefit patients in terms of increased mobility. One participant responded: "if they have their own wearable device, um, obviously they can bring it to travel, is easier. Um, so there's less paperwork of transferring information to an in-center dialysis. They can just have their own wearable machine. Um, they can do it while doing errands. They can do it

at work. They can do it while they're out on vacation with family" (CL30). Such treatment modifications bring the opportunity for increased mobility as the patient would no longer be required to spend multiple hours several times per week connected to a stationary device. As a result, the patient would gain greater freedom of movement that would bring them greater opportunities to partake in physical and social activities, seeking education, work, and travel.

The participants also talked about how a wearable hemodialysis device can improve a patient's quality of life. Assuming optimal designs of a wearable device, the device would allow the patient even further autonomy and discretion while doing dialysis. One participant indicated "I think that it is going to change their quality of life, making them able to feel somewhat normal – kind of like normalize their disease process. No longer is it a burden where you're either having to go to the center or having to carry something around. It becomes like a natural progression." Another participant responded "I think a wearable device is where we should try to go from here forward because that's really what patients I think are waiting for. Like a wearable kidney almost. I don't think dialysis would be as scary for them if they knew that, 'Hey, I could wear this device, but I could still carry on with life.' I think for that population they feel like dialysis is the end all be all for them. When it doesn't have to be."

The participants also mentioned how the patients would obtain greater control over their treatment schedules and be able to conveniently choose both the timing and the location of their treatment. The participants further talked about how the wearable dialysis device may help improve a dialysis patient's health outcomes. For example, a patient would have the opportunity for longer and gentler dialysis compared to what current in-center treatments can offer. One participant responded: "Your clearances would be better. Your quality of life would be 100 times better because it would be more like a home hemo. More dialysis is better dialysis. So, the current standard of four hours three days a week is not enough to – it's enough to keep you alive. It is not enough, necessarily, to keep you alive and feeling well." Slower dialysis, also called low flow dialysis, more closely resembles normal kidney functioning thereby offering a patient the potential for better fluid management, fewer dietary restrictions, fewer medications, and ultimately less hospitalization.

Table 6.1: Categories of nephrology nurses' perspectives of the benefits to patients afforded by a wearable hemodialysis device.

Categories (*Sub-categories*)	Formulated Description	Number of Comments
Mobility		47
Movement	Freedom of movement by not being connected to a stationary device.	16
Travel	Improved ability to travel.	8
Work	Improved ability to seek work.	7
Socializing	Improved ability to socialize with family and friends.	5
Activities	Improved ability for physical and daily living activities.	11
Exemplary quotation	"You could go and do anything. You could sit at work. You could go to the beach. You could just – do just about anything." -CL02	
Quality of Life		37
Time	Freedom of time.	11
Normalcy	Greater normalcy of life.	16
Diet	Less restrictive diet.	3
Sleep	Improved sleep.	1
Burden	Relieves disease burden.	3
Privacy	Improved privacy with less social stigma.	2
Self-esteem	Gain self-esteem.	1

Table 6.1 continued from previous page

Categories (*Sub-categories*)	Formulated Description	Number of Comments
Exemplary quotation	"they would have a normal life. They would almost have a kidney or a transplant. I would imagine that they're diet would be, in either scenario, diet would change. That their ability to fluid control may change. Um, what they can eat when they can eat, how they can eat. It just ... all of it. Um, they become normal." CL31	
Treatment		27
Treatment location	Flexibility of treatment location.	9
Treatment timing	Flexibility of treatment timing.	7
Control over therapy	Improved self-management of treatment.	11
Exemplary quotation	"Well, obviously, they'd be able to do longer, gentler dialysis." -CL23	
Health Outcomes		9
Feel better	Patients' feel better overall.	1
Vital signs and cleanings	Less shocking hemodynamically with improved vital signs and blood cleanings.	6
Kidney function	Preserves residual kidney functioning.	1
Medication	Fewer medication.	1
Exemplary quotation	"You could do a dialysis treatment, a longer, more gentle dialysis treatment throughout the day, um, which helps preserve, um, residual kidney function, um, I think that would be an advantage." -CL18	

6.1.3 Barriers to Recommending a Wearable Dialysis Device

The content analysis of participants' responses suggests five categories of potential barriers preventing nurses from recommending a wearable dialysis device to their patients. The identified categories and sub-categories of potential barriers to recommendation along with formulated category description and the number of comments related to each device type are displayed in Table 6.2.

Most commonly, the potential barriers were related to the devices' characteristics including a device that was difficult to set up and operate, keep clean, attach to the patient's bloodstream, and dispose of waste and fluids. One participant indicated: "It be simple to use, sort of intuitive, and easy to troubleshoot." The participants also talked about barriers related to the device's lack of accommodating patients' characteristics. A device that assumes a uniform patient population and does not adapt to patients' characteristics such as different body shapes and sizes, patients' levels of autonomy, dexterity, or sensory including visual, aural, or lingual abilities. Such designs would prevent the nurses from recommending the device to their patients.

The participants also talked about barriers related to the safety and efficacy of the wearable device. Commonly mentioned safety barriers included a lack of infection control and secure blood connections. The nurses were also concerned with patients' hemodynamic stability and the risk of damaging patients' vascular access while using a wearable dialysis device. One participant responded: "Is there a needle involved where it can dislodge? Having heavy equipment on your body and then having a delicate needle connected to it, how do you keep it safe? What happens if you get your access wet? Can it dislodge the needle?" Another participant said: "If the patient can move around with this thing, how do you prevent it from bumping into something or turning around and something gets caught in the doorknob or anything along that line? How do you prevent (it) from disconnecting, dislodging, damaging the access?" In terms of the efficacy of treatment, the participants were concerned with the level of dialysis a wearable device could offer the patient. One participant said: "Because it's smaller, I'm associating smaller with maybe not as much dialysis that could occur. This might just be the way I'm looking at it." Another participant stated: "Some of the barriers

for it would be if it's not as effective as other modalities or devices or other products on the market.".

The participants also talked about barriers related to the patient's geographical and social environment. The participants were concerned that the device would only be accessible in some geographical locations or to certain patient populations. Other participants talked about the patient's dwellings commenting: "Just do they have a clean private place where they could do the dialysis and be able to plug it into electricity? Those kinds of basic things."

Table 6.2: Categories of barriers preventing nephrology nurses from recommending a wearable dialysis device to their patients.

Categories *(Sub-categories)*	Formulated Description	Number of Comments
Device design		60
Device characteristics	Device is technically complex, not user-friendly, too cumbersome, hard to keep clean, lacks portability, lacks adequate battery lifetime, hard to attach to the patient, does not withstand impacts of accidents, hard to dispose of waste and fluids, and ties up main water source.	50
Patients' characteristics	Device does not adapt to patients' abilities including patients' level of dexterity, eyesight, mobility, age, native language, body shape, environment, or type of vascular access.	10
Exemplary quotation	"The biggest challenge is how big that wearable device is. Again going back to, you know, if it's this big, bulky item that they don't want on their – on their body." -CL04	
Safety and Efficiency		31

Table 6.2 continued from previous page

Categories *(Sub-categories)*	Formulated Description	Number of Comments
Safety	Lack of safety features for device functioning and blood connections including infection control, air in blood, and blood leak control.	21
Treatment efficiency	Lack of treatment efficiency and quality of dialyzing fluids.	10
Exemplary quotation	"Especially that the needles are, um, safely attached so the lines, all that, that there's a safe attachment so they are free to move about without dislocating any – any lines or needles." -CL05	
Treatment support and Training		16
Care support	Lack of care support at home and from provider. Lack of remote monitoring features and procedures.	5
Device support	Lack of timely device replacement, device use support, and access to supplies.	4
Instructional procedures	Lack of training, evaluations, and follow-up procedures.	7
Exemplary quotation	"The ease of teaching how to, um, how to run it and understand it and learn." -CL16	
Self-management and Environment		9
Compliance	Lack of self-care and treatment compliance.	5
Housing and privacy	Lack of access to safe housing with access to electricity or battery power, a clean water source, and privacy.	4

Table 6.2 continued from previous page

Categories *(Sub-categories)*	Formulated Description	Number of Comments
Exemplary quotation	"Someone who wasn't willing to follow the orders, um, uh, homelessness, mental illness, those sorts of things. Um, someone who wasn't, uh, very clean, because I – I would imagine you would have to be diligent in your cleaning practices." -CL24	
Accessibility and Affordability		4
Geographical accessibility	Lack of geographical accessibility of the device for all.	2
Cost and coverage	Lack of affordability of the device for all.	2
Exemplary quotation	"I think financial because I'm not sure if that's affordable. You know, if it's affordable enough for everyone to have it." -CL20	

6.1.4 Ideal Features of a Wearable Dialysis Device

The nurse participants talked about design features that a wearable hemodialysis device should hold to ensure the nurses feel comfortable recommending the devices to their patients. Inductive content analysis of participants' responses suggested seven categories of ideal design features. The categories and sub-categories of ideal features of a portable and a wearable dialysis device along with formulated category description and the number of comments related to each device type are displayed in Table 6.3.

The participants consistently mentioned ideal features ensuring patients' safety while using a wearable hemodialysis device. One participant said: "From a safety standpoint, if you wear it, it needs to be attached in a very safe way so it can't move about or drop to the floor." Another participant stated: " Safety in it that if somebody came up and knocked them or hit them or even bumped into them, it would not, um, throw the machine off or

throw the – throw the device off or make – or disconnect something". Yet another participant said: "Since you're wearing it and you're doing dialysis and you're doing work, um, what are the safety features that would make you, like, "Oh, there's something happening. Oh, you're – this is – this, um, the problem." So, is there a sound? Or is there something that you very feel for it to be safe?".

The participants also talked generously about features ensuring the ease of using the device. Ideal device characteristics would enable users to operate the device in an intuitive way without hindrance or uncertainty. One participant said: "I would like to see something where it would be very, very easy for the patient to attach." Another participant stated: "Easily to understand, easy to use, um – under, you know if there's any [...] things they need to understand about it, that they're easy [...] concepts that are easy for them to understand and to, uh, put into place." Ideal design features related to the efficiency of treatment were also identified. One participant said: "Does it meet the – the same standards that you know, um, that they would get um, as you know, their home therapy machine gives them. That's – that's the biggest thing." The participants further talked about features of treatment monitoring and display for the wearable dialysis device. One participant said: "I think because it's a wearable device, I'd really want to – as a nurse – be able to receive information as it's happening. I'm not sure if that's something that is possible. Where information is constantly being uploaded into an iCloud or some sort where I'm able to log in and/or it alerts me. 'Hey. We're having really low blood pressures.' Or, you know, some sort of alert where we're able to immediately address it. Especially if they're wearing it." Similarly, another participant commented: "It has Bluetooth capabilities, or wi-fi capabilities to take data and monitor changes in certain intervals because a person wants to remain active and not take data manually. And it can alert the person to changes based on set parameters from time to time to indicated that there could be problems."

Table 6.3: Categories of nephrology nurses' perspectives of ideal design features of a wearable hemodialysis device.

Categories *(Sub-categories)*	Formulated Description	Number of Comments
Safety		28
Operation	Device ensures safe blood connections and prevents harmful and unintentional operation with locking features and automatic shut-down.	20
Sterility	Device has infection and contamination control.	4
Secure wearing	Device is secure while wearing and does not drop.	3
Self-contained	Device is safe with adults, children, and pets around with no lines that can be tangled or snagged.	1
Exemplary quotation	"I think there needs to be a safety – like, you obviously don't want it to – to drop. Especially not while in use because you don't wanna tug on their catheter or their needles. So, some sort of safety belt or safety whatever." -CL01 "I'm thinking about people going to the beach, the pool, you know, wherever, it would have to be just completely airtight that nothing's getting in there. You know infection being an enormous issue for our patients.." -CL08	
Aesthetics and Design		27
Compactness	Device is small sized and lightweight.	12
Design forms	Ideal design forms suggested: a shoulder bag, a cross body bag, a vest design, and a streamlined design.	5

Table 6.3 continued from previous page

Categories *(Sub-categories)*	Formulated Description	Number of Comments
Noticeability	Device is not noticeable to the public, discreet in terms of sounds and smell, yet clearly marked as a life sustaining device.	8
Storability	Device is easy to store and access.	1
Materials	Device is made with durable components and materials.	1
Exemplary quotation	"It would have to be comfortable and light. It can't be too heavy for them. Yeah, a lot of patients have a lot of issues. So, very comfortable, light. Um, and I think probably being able to conceal it would be important to them." -CL28	
Ease of Use		24
Device characteristics	Device is simple and easy to operate, easy to set up and take down, easy to connect to the bloodstream, easy to clean and dispose of waste, and easy to troubleshoot. Ideally interactive.	20
Patient' characteristics	Device can be independently used by the patient and adaptable to patients' individual characteristics including impaired vision or hearing and different body shapes.	4
Exemplary quotation	"Easy to understand, easy to use" -CL04	
Display and Monitoring		22
Interface	Device is easy to read with simple functionality, message, and alarm indicators.	8
Treatment parameters	Device displays treatment parameters and timing with summary recording and reporting.	6

Table 6.3 continued from previous page

Categories *(Sub-categories)*	Formulated Description	Number of Comments
Vital signs	Device displays patients' vital signs including heart rate, blood pressure, and temperature.	2
Remote monitoring	Device allows for online remote monitoring of patients' treatment information from clinic or by care partner.	6
Exemplary quotation	"Um, some kind of ability to monitor the, uh, you know, the – the staff would be able to monitor what the patient is doing." -CL14	
Efficiency		21
Durability	Device has durable mechanics that withstands climate changes with adequate battery life.	4
Treatment	Device is time and treatment efficient, providing equal or better treatment as current devices.	13
Dialysates	Device ensures adequate dialysate quality and efficiency of used fluids.	1
Reliability	Device provides reliable treatment each time.	3
Exemplary quotation	"Um, battery life, I mean, if it has a battery, how long before you have to be plugged into something? You know, how long can you – can you last? Can you do, you know, a – an eight-hour workday or walk around the park or something like that?" -CL11	
Mobility		11
Wearability	Device is easy and comfortable to wear and does not restrict the patients' mobility.	11
Exemplary quotation	"I'd wanna be able to move back and forth easily. I'd want to be able to – and I know this may sound stupid – but bend over and get my laundry out." -CL07	

Table 6.3 continued from previous page

Categories *(Sub-categories)*	Formulated Description	Number of Comments
Support and Training		6
Device support	Easy access to device use support, ease of part replacement and supplies.	2
Learning	Easy to learn how to use the device and understand how the device functions.	4
Exemplary quotation	"I think, being able to learn how to use the machine, the ease of learning it and running it, um, would be the big thing with our patients." -CL16	

6.1.5 Preferred Design Type of a Wearable Dialysis Device

The nurses were asked to rank five different design types of a wearable dialysis device; a belt, a backpack, a vest, a shoulder bag, and a distributed design (a modular design where different components of the device would be carried or placed on different areas of the patients' body). The responses were in terms of rankings on a scale from one to five, with one being the least preferred design type and five being the most preferred design. As shown in Table 6.4, results from Friedman testing show a statistically significant difference between nurses' preferred design types ($\chi^2 = 12.2$, $p = 0.0162$). Using Conover post-hoc analysis with the Hochberg adjustment method to control for familywise type I error, our results show that the nurses significantly preferred the belt design over the distributed design ($p < 0.01$). Other than the two design types, the post-hoc analysis did not show any significant pairwise comparisons.

Table 6.4: Nephrology nurse's wearable design preference rankings.
The higher the ranking number, the more preferred design type.

Design Type	n	Median	Mean (SD)	95% CI
Backpack	32	3	2.95 (1.35)	[2.47, 3.44]
Belt	32	4	3.77 (1.45)	[3.25, 4.30]
Distributed design	32	2	2.41 (1.58)	[1.84, 2.98]
Shoulder bag	32	3	2.94 (1.27)	[2.48, 3.40]
Vest	32	3	2.94 (1.13)	[2.53, 3.35]

6.1.6 Discussion and Conclusions

To the best of our knowledge, this study is the first to explore and characterize nephrology nurses' perspectives of a wearable hemodialysis device, using a human factors engineering approach. Nephrology nurses' views of different modalities of hemodialysis treatments and patients' options in choosing treatment were investigated as well as the potential benefits of a wearable hemodialysis device. This study also explored the ideal design features of a wearable hemodialysis device, potential barriers that may exist hindering nephrology nurses from recommending a wearable hemodialysis device to their patients, and the most preferred design type of a wearable hemodialysis device.

Exploring nephrology nurses' views on treatments alternative to in-center hemodialysis, the findings from this study show that the respondents believe that increased frequency and home-based hemodialysis provide patients with greater quality of life and improved clinical outcomes. While some nurses believe patients prefer in-center treatments for the reason of having a clinician oversee their treatment, the findings show that most nurses did not support that reasoning. These findings are in line with findings from previous studies exploring nephrologists' perspectives [61]. Despite support for treatments alternative to in-center hemodialysis, only 1.8% of all hemodialysis patients in the U.S. perform treatments in their homes [203]. Although the findings demonstrate that nephrology nurses have positive

attitudes toward home-based dialysis, it is perplexing that so few patients successfully adopt and experience the benefits of home-based treatments. One reason might be that current treatments assume a homogeneous patient population and should be more individualized, a statement supported by most of the nurse participants. Another potential reason identified in the literature states that patients still carry a high symptom burden with restricted mobility during their home dialysis treatments [88]. Nearly unanimously, the nurse participants believed that a wearable hemodialysis device has the potential to benefit patients emphasizing increased mobility, enhanced quality of life, and improved health outcomes.

Building on previous work, these findings show that nephrology nurses share many perspectives with those of patients and care partners [97]. For example, the current and previous participant groups all highly emphasized the importance of including features ensuring patients' safety while using the device. Most nurse participants were concerned over patients' safety and the efficacy of treatment while using a wearable dialysis device. To overcome some of their concerns, the nurses emphasized the importance of including an array of safety features and a system that provides the nurses with the ability to monitor patients' mobile dialysis treatments remotely from the dialysis center. Such features may help ensure and support patients' safe and independent use of their mobile dialysis devices.

The nurses also talked in detail about designing a user-friendly device that is adaptable to patients' characteristics and that patients feel comfortable using during their daily routines. Other shared perspectives included ensuring support for the patient while doing a wearable hemodialysis treatment, including an efficient patient monitoring system, and ensuring durable and appealing designs while at the same time ensuring patients' privacy with discreet designs. The findings from exploring ideal design forms of the wearable hemodialysis showed that the nephrology nurses significantly preferred the belt design over the distributed design similar to previous findings exploring patients' preferences [97].

The perspectives and responses of the nephrology nurses also differ in many ways from those of patients and care partners. The results show more detailed preferences for treatment specifications and treatment parameters for the wearable hemodialysis devices from the nephrology nurses compared to those of patients and care partners. To be noted is that the nurses' perspectives are generally in terms of their entire patient population compared to

patients' and care partners' individual preferences. As a result, the findings from this study may present a broader insight into ensuring equity for all patients in wearable hemodialysis designs. Some of these factors include ensuring a design that accommodates patients' diverse characteristics and the importance of affordability and accessibility of the device for all.

Several study limitations exist that guide future research directions. First, although this study aimed to recruit a diverse sample of participants, by recruiting participants across 16 U.S. states, the participants were still of low demographic diversity. As a result, the views and perspectives of the study participants may not be generalizable and represent the perspectives of other nephrology nurses. Secondly, as the wearable hemodialysis device is currently in the early design conceptualization stage and not yet on the market it may have been difficult for the participants to envision an ideal device design and potential risks to the patients. Additionally, all participants were interviewed over a virtual computer-based platform which may have caused a potential limiting influence on the provided responses.

The findings from this study have important implications both for the nephrology nursing community and the research and engineering community. First, there is a need to continue to include nurses' perspectives on the designs of healthcare technology particularly during the early stages of designs and development. The needs and expertise of nephrology nurses are integral to the success of new products being brought to market. Their healthcare expertise along with their proximity to patients' experiences offer a vision of design factors to be accommodated and help set and refine the design and usability goals to ensure users' safe and effective interaction with wearable dialysis devices (Smith et al., 2019; Castner et al., 2016). The results of this study will help guide design solutions based on nephrology nurses' perspectives. The input from nephrology nurses in this study offers a vision for the most ideal designs of a wearable hemodialysis device that clinicians feel comfortable recommending to their patients. This vision includes several components including ideal shapes and form factors of the devices; ideal features of the device, and potential barriers that may prevent the nephrology nurses from recommending the device to their patients. As human-centered design has become recognized as a crucial aspect of successful product development, future studies should continue to integrate nephrology nurses' perspectives throughout the development of wearable hemodialysis technology. Future studies should

also aim to gather the perspectives of more diverse user groups, including those of patients, care partners, nephrologists, and nephrology nurses.

6.2 Nephrologists' Perspectives for the Designs of a Wearable Dialysis Device

6.2.1 Nephrologists' Perspectives on Mobile Dialysis Treatments

Figure 1 displays nephrologists' perspectives on in-center, home-based, portable, and wearable hemodialysis modalities; treatment modification; and training and monitoring procedures. The nephrologists were asked to respond to statements corresponding to hemodialysis options and prescriptions (Questions 1–4 in Figure 1). Most nephrologists either agreed or strongly agreed that they would try their best to convince their patients to choose the treatment modality that would provide the best clinical outcomes and quality of life, even though the patients may be nervous about trying that particular modality (97%). Most nephrologists also either agreed or strongly agreed that currently limited treatment choices for patients are available (60%) and that current dialysis treatments are indifferentiable and should be more individualized according to patients' needs (80%). However, conflicting responses were observed when the nephrologists were asked if all patients are given the same opportunity to choose their preferred mode of treatment, with 46% either disagreeing or strongly disagreeing and 44% either agreeing or strongly agreeing.

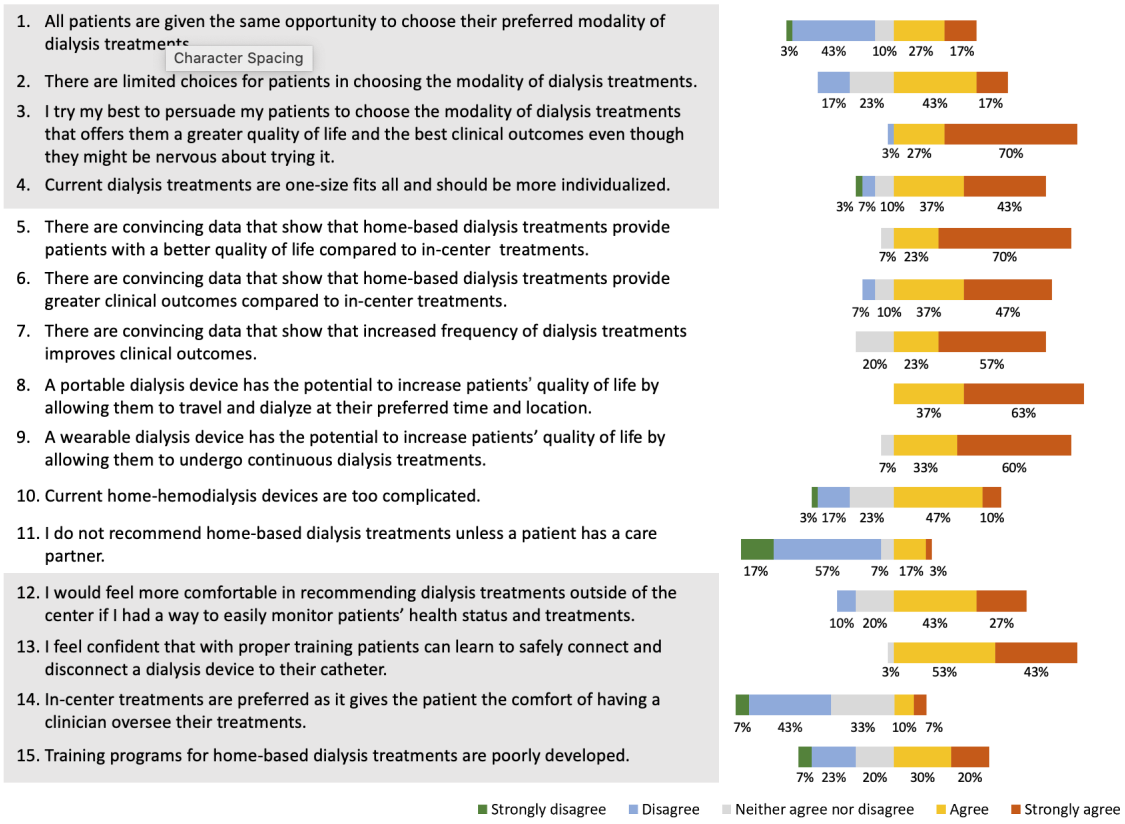

Figure 6.2: Nephrologists' perspectives towards dialysis modalities, home-based dialysis programs, treatment modification, and portable and wearable dialysis devices.

The nephrologists most frequently either agreed or strongly agreed with statements that were positively directed towards home and mobile hemodialysis treatments (Questions 5–11 in Figure 1). The nephrologists believed that home hemodialysis provides patients with increased quality of life and improved clinical outcomes compared to in-center treatments (93% and 84%, respectively). They also believed that increased frequency of dialysis improves patients' clinical outcomes (80%). Most nephrologists disagreed with the statement that they do not recommend home dialysis treatments unless a patient has a care partner (74%), yet, most nephrologists also believe that current home hemodialysis devices are too complicated to use (57%).

All nephrologists believed that a portable hemodialysis device has the potential to in-

crease patients' quality of life by providing them with the ability to perform more frequent dialysis and to travel (100%). Similarly, most nephrologists either agreed or strongly agreed that a wearable hemodialysis device has the potential to increase patients' quality of life by providing them with the opportunity to perform continuous dialysis treatments (93%). Statements intended to explore nephrologists views on training and monitoring programs for home hemodialysis showed mixed responses (Questions 12-15). Most nephrologists indicated that would feel more confident in recommending home hemodialysis programs if they had a way to easily monitor patients' health status and treatment (70% either agreed or strongly agreed). Most nephrologists also indicated that they would feel confident that with proper training patients can learn to safely connect and disconnect a dialysis device to their catheter (96% either agreed or strongly agreed). At the same time, half of the nephrologists indicated that current home hemodialysis programs are poorly developed (50% either agreed or strongly agreed). Most nephrologists disagreed that in-center treatments are preferred because it gives the patient the comfort of having a clinician oversee their treatments (50% either disagreed or strongly disagreed).

6.2.2 Benefits for Patients Afforded by a Wearable Dialysis Device

Inductive content analysis suggested five main categories of benefits to patients of having a wearable hemodialysis device. Table 6.5 displays the five categories along with their respective subcategories and descriptions, as well as the number of comments associated with each subcategory. Table 6.5 also presents the total number of comments made under each category to capture frequently mentioned categories and exemplary quotations. The categories and subcategories are arranged in descending order based on the total number of comments each received.

Table 6.5: Categories of nephrologists' perspectives of the benefits to patients afforded by a wearable hemodialysis device.

Categories (Subcategories)	Formulated Description	Number of Comments
Mobility		42
Movement	Increased movement.	17
Work	Improved ability to go to work.	6
Travel	Improved ability to travel.	2
Activities	Improved ability for physical and daily living activities.	11
Socializing	Improved ability to partake in social events with family and friends.	6
Exemplary	"The ability to move from place to place would really be a huge, huge step forward." (DR04)	
Treatment		23
Treatment location	Flexibility of treatment location.	7
Treatment timing	Flexibility of treatment timing and duration.	11
Control over therapy	Improved self-management of treatment.	2
Treatment modification	Reduced treatment complexity.	1
Gentleness	Gentler dialysis (slow and smooth).	2
Exemplary	"I mean as you pointed out, being able to dialyze when you want, where you want. Instead of being tied to a center at the discretion or the scheduling time of the treatments. That would be one big plus." (DR14)	
Quality of Life		19
Freedom	Greater freedom.	5
Quality of life	Improved quality of life.	3
Diet	Less restrictive diet.	4

Table 6.5 continued from previous page

Categories (Subcategories)	Formulated Description	Number of Comments
Independence	Improved independence.	1
Comfort	Greater physical comfort.	2
Privacy	Improved privacy with less social stigma.	2
Convenience	More convenient.	1
Sleep	Improved sleep.	1
Exemplary	"If it obviates the need for sitting in a dialysis chair, whether it's at a center or at home for a long period of time, whether that's two or three hours or four or five hours, that's a huge benefit in terms of time and lifestyle freedom." (DR17)	
Health Outcomes		15
Kidney function	Mimics kidney function.	6
Health	Improved health outcomes.	3
Feeling better	Patients' feeling better overall.	3
Hospitalization	Less hospitalization.	1
Medication	Fewer medications.	1
Exposure to diseases	Less exposure to diseases through hospitalization.	1
Exemplary	"Hopefully, that means more frequent dialysis, longer dialysis sessions, which we know are tied to better outcomes." (DR23)	
Storage		1
Supplies and storage	Reduced supplies and storage requirements.	1

Table 6.5 continued from previous page

Categories (Subcategories)	Formulated Description	Number of Comments
Exemplary quotation	"With a patient, they have to use the whole room to store all the supplies, and this portable, small, battery-based portable device is a huge plus I would say in terms of the space." (DR08)	

Most frequently, the nephrologists focused on the benefits of patients' increased mobility. The nephrologists mentioned the ability for increased movement, and improved ability to seek employment potential and to travel. The second most frequently mentioned benefit concerned wearable hemodialysis treatments. The nephrologists highlighted the benefits of having the flexibility of treatment timing and location where patients obtain control over their treatment schedules. Other frequently mentioned benefits of a wearable hemodialysis device included improving patients' quality of life and health outcomes.

6.2.3 Barriers to Recommending a Wearable Dialysis Device

Six main categories of potential barriers were identified concerning nephrologists recommending a wearable hemodialysis device to their patients. Table 6.6 displays the categories and subcategories defining the specific barriers nephrologists anticipated. The number of comments that fell under each category and some exemplary quotations are provided for each device.

The nephrologists most frequently mentioned barriers involving the perceived safety and efficacy of the device where the nephrologists talked about the risk of blood loss, infection, and damage to patients' vascular access. Moreover, the nephrologists expressed skepticism regarding the capability of a wearable hemodialysis device to deliver efficient treatment. The second most frequently mentioned barrier involved the design of the device including the compactness of the device, lack of monitoring features, and failure to support patients' individual needs in facilitating the ease of use.

Other barriers to recommendation included the accessibility of the device, patients' self-management of treatment, support, and training. Within those categories, the nephrologists were primarily concerned about complicated training procedures, patients' self-sufficiency, patients' reluctance to try a new treatment method, and nephrologists' inability to persuade them to do so.

Table 6.6: Categories of barriers preventing nephrologists from recommending a wearable dialysis device to their patients.

Categories (*Subcategories*)	Formulated Description	Number of Comments
Safety and Efficacy		22
Safety	Lack of safety features and blood access control.	15
Treatment efficacy	Efficacy inferior to that of current treatment alternatives.	7
Exemplary quotation	"Safety would be a big thing. How is it accessing the blood. How is it working? If you're talking needles, needles can come out if patients are walking around. How is it gonna access the bloodstream? You know, patients are walking around. You've got a lot less control over the stability of the situation and the risk for infection, the risk for bleeding. Those would be my biggest concerns." (DR07)	
Device Design		10
Patient characteristics	Lack of support for patients' cognitive and visual impairment, dexterity.	4
Device characteristics	Fragility, weight, and size of device; ease of use; remote monitoring and feedback; visibility on body.	6

Table 6.6 continued from previous page

Categories (*Subcategories*)	Formulated Description	Number of Comments
Exemplary quotation	"Maybe patients have significant dexterity or visual problems. I would be relatively concerned with those folks unless they had a very responsible caregiver." (DR19) "I think there's going to be a psychological barrier for a lot of patients. There are some patients who would benefit and embrace the freedom and the mobility that comes with it. There's a lot of other patients who just don't want to have their business out there and be walking around with a dialysis machine for the world to see." (DR17)	
Accessibility		9
Cost	Cost, lack of financial reimbursement.	5
Accessibility	Accessibility and portability of the device.	1
Options	Availability of different designs.	3
Exemplary quotation	"Accessibility, who is going to pay for it? That's the biggest barrier in medicine for us is like how hard is it for this to get paid for? We all know [cost] drives a lot of medical decision-making and it has to be accessible. It has to be covered by our traditional insurances and the patient shouldn't have to jump through a lot of hoops" (DR16)	
Self-Management		9
Self-sufficiency	Patients' lack of self-monitoring behaviors and dedication; inability to take medicine consistently; burnout.	7
Patients' attitudes	Patients' fear of managing treatments on their own.	1

Table 6.6 continued from previous page

Categories (*Subcategories*)	Formulated Description	Number of Comments
Nephrologists' attitudes	Nephrologists' concerns about their ability to convince patients to try mobile treatments.	1
Exemplary quotation	"Sometimes it's the burnout, um, of, you know, having to do this themselves. The fear of what if something happens here? There is someone else in the center versus what if something happens when I'm doing it alone? What if I pass out, have a syncopal episode, and who will call 911? You know, things like that. Concerns about complications during treatment, patient concerns." (DR11)	
Treatment Support and Training		6
Instructional procedures	Patient education, care partner education, nursing education, ease of training.	5
Device support	Lack of device maintenance services, lack of nationwide support.	1
Exemplary quotation	"I mean, it is something that is intuitive and has a good set of instructions. Will it be able to have an appropriate patient care staff who can get familiar enough with it to actually educate the patients on it?" (DR29)	
Reliability and Trust		4
Reliability	Concerns about treatment reliability, alarm stopping working, limited battery life.	4
Exemplary quotation	"I think if there was a piece that was implantable that didn't have a track record of being reliable, I would be concerned about that." (DR12)	

6.2.4 Ideal Features of a Wearable Dialysis Device

Content analysis of the nephrologists' comments regarding a wearable dialysis device yielded seven categories of ideal features. Table 6.7 presents the number of comments nephrologists made about the ideal features of a wearable device; it also presents exemplary quotations. The categories of aesthetics and design received the most comments where the nephrologists emphasized the importance of a small and lightweight design that is not noticeable to the general public yet identifiable as a life-sustaining device.

The second most mentioned ideal features were related to the display and treatment monitoring with safety following close behind. The nephrologists highlighted the importance of simplicity in use, including remote monitoring of patient's treatment information and vital signs. The nephrologists also highlighted the importance of ensuring the safety of the device with infection and contamination control and a user-friendly way of accessing patients' blood supply.

Table 6.7: Categories of nephrologists' perspectives of ideal design features of a wearable hemodialysis device.

Categories (*Subcategories*)	Formulated Description	Number of Comments
Aesthetics and Design		30
Compactness	Device is small and lightweight.	18
Noticeability	Device is not noticeable to the public and discreet in terms of sounds and smell, yet it is clearly marked as a life-sustaining device.	12
Exemplary quotation	"It should not be too big, because it is portable, so I'd probably say, weigh no more than 8 or 10 pounds." (DR06)	
Display and Monitoring		25

Table 6.7 continued from previous page

Categories (*Subcategories*)	Formulated Description	Number of Comments
Interface	Device is easy to read with simple functionality and alarm indicators.	10
Remote monitoring	Device allows for online remote monitoring of patients' treatment information by clinic or by care partner.	6
Treatment parameters	Device displays treatment parameters and timing with summary recording and reporting.	4
Vital signs	Device displays patients' vital signs including heart rate, blood pressure, and temperature.	5
Exemplary quotation	"Definitely has to have large machines, large buttons, cannot be very technically involved because that's a big barrier for patients." (DR07)	
Safety		23
Blood access	Device ensures safe and easy blood connections.	8
Safety	Device is safe to use.	9
Sterility	Device has infection and contamination control.	5
Water system	Device has a small water supply and purification system.	1
Exemplary quotation	"As always with any new device, is always safety, patient safety is of greatest concern." (DR19)	
Efficiency		16
Treatment efficacy	Device is time- and treatment-efficient, providing equal or better treatment compared to current devices.	11
Durability	Device has durable mechanics that withstand changes in climate with adequate battery life.	4
Reliability	Device provides reliable treatment.	1

Table 6.7 continued from previous page

Categories (*Subcategories*)	Formulated Description	Number of Comments
Exemplary quotation	"It needs to be able to deliver dialysis in an efficient fashion, at least equivalent to what the current in-use dialysis modalities are." (DR16)	
Usability		16
Ease of use	Device is simple and easy to operate, easy to set up and take down, easy to connect to the bloodstream, and easy to clean and empty of waste.	8
Comfort	Patient is comfortable when using this machine.	8
Exemplary quotation	"The ease of hooking up has to be quite easy. So, it cannot be too complex or cumbersome and it should be in such a way that it doesn't put off people who accidentally stumble upon this person doing their dialysis." (DR26)	
Mobility		5
Wearability	Device makes it easy to do day-to-day activities.	5
Exemplary quotation	"It has to be portable and easy in the sense that anywhere they want, wherever they want, they can just go ahead and do the dialysis." (DR02)	
Support and Training		3
Device support	Easy access to device user support, easy part replacement and supply procurement.	2
Training	Easy to learn how to use the device and understand training procedures.	1
Exemplary quotation	"Ease of learning for the patient and for the care team involved." (DR28)	

6.2.5 Preferred Design Type of a Wearable Dialysis Device

To gain insight into the nephrologists' most preferred wearability designs for ESRD patients, we asked the nephrologists to rank five proposed design types of a wearable hemodialysis device. This question was intended to elicit information that could then be used to guide initial prototype development, focusing on aspects of device miniaturization and technical challenges related to different wearability form factors. Table 6.8 shows summary statistics of nephrologist's rankings of the five proposed designs of a wearable hemodialysis device. Friedman's testing of participants' preference rankings showed a statistically significant difference between preferred designs ($\chi^2 = 20.4$, $p < 0.001$) with a small effect size ($\tau = 0.17$). Conover post hoc analysis with the Hochberg adjustment method to control for family-wise type I error showed that the participants significantly preferred a belt design over a distributed design ($p < 0.0001$), a shoulder bag design ($p < 0.0001$), or a vest design ($p < 0.05$).

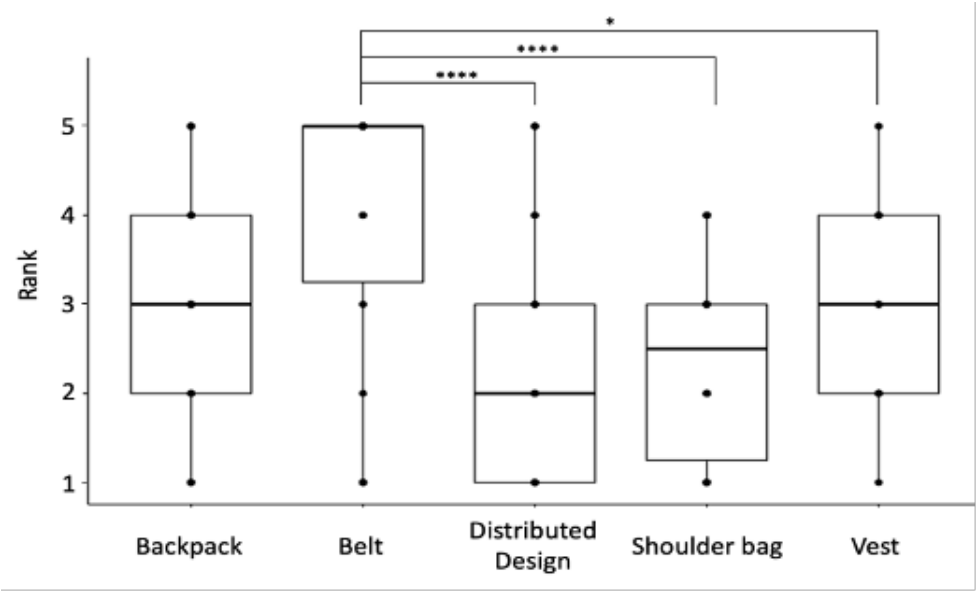

Figure 6.3: Box plots indicating the participants' rankings of proposed design types of a wearable dialysis device. A higher average ranking indicates a more preferred design type. * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$, **** $p < 0.0001$

Table 6.8: Nephrologist's wearable design preference rankings.
The higher the ranking number, the more preferred design type.

Design Type	n	Median	Mean (SD)	95% CI
Backpack	30	3	3.13 (1.28)	[2.68, 3.59]
Belt	30	5	4.00 (1.55)	[3.44, 4.56]
Distributed design	30	2	2.40 (1.45)	[1.88, 2.92]
Shoulder bag	30	2.5	2.43 (1.10)	[2.04, 2.83]
Vest	30	3	3.03 (1.10)	[2.64, 3.43]

6.2.6 Discussion and Conclusions

Using HFE methods, this study focused on identified nephrologists' perspectives toward the designs of a wearable hemodialysis device. The HFE approach was used to complement previous research gathering patients', care partners', and nephrology nurses' perspectives and generate a more holistic understanding of preferred device designs and implementation strategies [99, 97, 98, 109].

Using a questionnaire, nephrologists' views were explored on treatment modalities, patient choices, and treatment prescriptions. By conducting in-depth interviews, this study identified the potential benefits to patients of having a wearable hemodialysis device, potential barriers to nephrologists' recommending the device, and the ideal features of the device. This research presents a detailed picture of nephrologists' perspectives on a wearable hemodialysis device, including their preferred design type.

The nephrologists in this study indicated they make every effort to convince their patients to consider treatment options that yield the best clinical outcomes and quality of life despite patients' apprehension about them. At the same time, many nephrologists acknowledged a dearth of treatment choices for their patients and indicated that current treatment options are generic and should be tailored to suit individual patients' needs. Interestingly, the nephrologists also acknowledged that patients are not given equal opportunity to choose their

preferred treatment option. Some nephrologists also reported that current home hemodialysis devices and training programs are too complicated for patients. Gathering nephrologists' perspectives on mobile hemodialysis devices, this study shows that nephrologists positively perceived a wearable hemodialysis device that may bring several benefits to patients, including improved clinical outcomes and increased quality of life. These findings resemble findings from the previous study exploring nephrology nurses' perspectives [98].

The exploration of the benefits a patient may derive from using a wearable hemodialysis device indicates similar categories of potential benefits as previously identified from exploring nephrology nurses' perspectives [98]. Additionally, the nephrologists talked about the benefit of reduced storage requirements for treatment supplies. A comparison of the mentioned benefits between nephrologists and nephrology nurses shows that the nephrologists talked more generously about the benefits of improved health outcomes frequently mentioning the benefit of a wearable device mimicking regular kidney functioning. On the other hand, the nephrology nurses talked more generously about the benefits of improved quality of life mentioning the benefits of relief from disease burden and patients' improved self-esteem.

A comparison of potential barriers to recommendations identified in this study to previously identified barriers by nephrology nurses shows that both groups identified the same categories of barriers but to different degrees [98]. Most frequently, the nephrologists were concerned with the safety and efficacy of the device expressing concerns about potential vascular dislodgement due to movement during treatment and reduced treatment effectiveness due to device miniaturization. Additionally, the nephrologists talked about barriers related to reliability and trust, raising concerns about documented long-term treatment and component reliability. In contrast, the nephrology nurses were most frequently concerned with barriers related to the devices' design characteristics worrying about the device being technically complex to operate, cumbersome, and lacking battery and material durability [98].

This study identified several relationships between ideal design features and barriers to implementation. Patients' safety, device compactness, and treatment support were found to be crucial aspects of a wearable hemodialysis device that the nephrologists would feel comfortable recommending to their patients. The findings also suggest that potential barriers

related to patients' lack of self-sufficiency and fear of wearable hemodialysis treatments may be overcome by focusing on designing a user-friendly interface and incorporating remote treatment monitoring procedures. By incorporating these features into the device design, researchers may help reduce barriers to recommendation while simultaneously facilitating users' acceptance of the device.

Exploration of nephrologists' preferred design types of a wearable hemodialysis device resembles those of the previous studies exploring patients' and nephrology nurses' preferences: all samples reported significantly preferring a device in the form of a belt [97, 98]. However, care partners were found to significantly prefer designs in the form of a vest [97].

Several study limitations exist that are worth noting. First, during the interview process, the nephrologists were initially asked about their perspectives regarding the designs of a portable hemodialysis device. A portable hemodialysis device is a mobile hemodialysis device that cannot be worn by the patient. The results from this study are presented elsewhere [7]. During the analysis process of the transcribed interviews, it became evident that the portable hemodialysis device generally received more comments compared to the wearable hemodialysis device. This is likely because nephrologists' perspectives were first gathered on a portable hemodialysis device before asking them questions regarding a wearable hemodialysis device. Consequently, when asked about the wearable device, the nephrologists may have assumed that the perspectives and attributes they had already identified for a portable device were self-evident and did not require reiteration for the wearable device. This interview order was chosen because the wearable hemodialysis device is considered to be a second generation of the portable hemodialysis device in terms of miniaturization of technology. Second, although the study aimed to recruit nephrologists with experience in diverse treatment options, the study participants had limited experience in managing home hemodialysis treatments. As a result, their perspectives may not be generalizable across all nephrologists. Additionally, as the wearable hemodialysis devices are in the early conceptual stages of development, no images of prototypes were presented to the participants. As a result, the level of concept visualization of the device may have differed among participants. It is noteworthy that HFE entails a design process in which participants' perspectives are to be iteratively gathered throughout the entire process, from idea conceptualization to final

prototype development. Future studies should aim to gather nephrologist's perspectives in parallel with advances in wearable hemodialysis device design.

The findings of this study have several implications for both the dialysis community and for wearable hemodialysis device developers. By characterizing nephrologists' perspectives, this study has provided support for previously identified design attributes and preferences from other user groups and reveals dimensions unique to nephrologists' professional vantage points. These findings help shed light on prioritized designs and needed implementation strategies for successful device adoption. Gathering perspectives from diverse user groups during the early stages of designing new technologies helps facilitate a deeper understanding of user needs, ultimately informing the development of targeted design solutions that can deliver value for both users and manufacturers.

Chapter 7

EXPLORING THE RELATIONSHIP BETWEEN USERS' CHARACTERISTICS, HUMAN FACTORS DESIGN PRINCIPLES, AND PROPOSED WEARABLE HEMODIALYSIS DEVICE DESIGNS

The objective of this chapter is to answer research question R4 by examining the relationship among users' demographic characteristics, human factors design principles, and wearable hemodialysis device designs. First, section 7.2 aims to explore the underlying latent structure of seven selected human factors design principles using exploratory factor analysis (EFA). EFA is commonly performed to select useful latent constructs for confirmatory factor analysis when little is known about the underlying structure of the data. Secondly, section 7.3 explores the relationship among the user demographic characteristics, human factors design principles, and five proposed design types of a wearable hemodialysis device. To explore these relationships, structural equation modeling (SEM) is conducted where the SEM incorporates the results from the EFA that form the basis of the measurement model in the SEM. The results of this study may help developers of a wearable hemodialysis refine their design processes based on a deeper understanding of the relationship between design aspects and users' individual differences.

7.1 Data Screening

Data from a total of 98 participants was used for exploratory factor analysis and structural equation modeling. The data comprised four participant groups, including 24 patients, 12 care partners, 30 nephrologists, and 32 nephrology nurses. Prior to conducting the EFA and SEM, the data was verified for value accuracy, missing data, and normality. Incomplete data from 5 participants were observed and were subsequently removed from further analysis. The results from a Shapiro test for data normality revealed deviations from normality. As a result, structural equation modeling with a full information maximum likelihood (FIML) estimator and Bootstrapping confirmation were chosen as the most appropriate and robust

structural equation modeling methods. To explore potential outliers, a Mahalonobis distance of χ^2 (15) = 37.6973, was used where one outlier was detected and subsequently removed from the dataset. The final data set for the EFA and SEM included 92 observations.

7.2 Exploratory Factor Analysis

Exploratory factor analysis (EFA) was conducted to investigate participants' perspectives and determine if human factors design principles share a common underlying structure. The EFA was conducted in five steps; data examination, choosing a factor extraction method, setting factor extraction criteria, setting factor rotation criteria, and factor interpretation.

7.2.1 Data Examination

The purpose of the data examination was to determine the suitability of the data for factor analysis. Two tests were conducted, the Kaiser-Meyer-Olkin (KMO) test to determine sampling adequacy and Bartlett's test of sphericity to determine sufficient correlations between variables. The results from the KMO test showed that 78% of the variance might be caused by underlying factors, indicating promising factor analysis results. The results from Bartlett's test suggested the correlations between variables were sufficiently large and the data could be compressed into fewer factors in a meaningful way (χ^2 (133.38), df = 21, p <0.001).

7.2.2 Factor Extraction and Analysis

After data examination, Principal Component Analysis was conducted on the seven variables representing the human factors design principles; ease of use, ease of connection, safety, accuracy, invisibility, comfort, and compactness. The results showed that the first two principal components explained almost 72% of the total variance in the data and Parallel Analysis suggested two underlying factors.

After deciding on the number of factors to retain, EFA was conducted using an oblimin rotation, allowing the factors to correlate. Using the cut-off criteria of factor loading greater than 0.3, the results from the factor analysis showed that the human factors design principles

of compactness, comfort, and invisibility jointly loaded on one factor while the principles of safety, accuracy, and ease of connection loaded on the second factor. Given that the principle of ease of use loaded on both factors (0.36, and 0.44, respectively), this principle was considered to be inefficient in measuring a single phenomenon and was removed from the analysis. The EFA was then performed again resulting in a simple structure where each principle had a loading greater than 0.3 on a single factor. The results showed that two factors are sufficient in presenting the data ($\chi^2 = 1.76, df = 4, p = 0.78$) and indicated a good model fit with RMSR = 0.02, RMSEA = 0.0 (90% CI [0, 0.105]), TLI = 1.11, CFI = 1.03. Examining the correlation between the two factors showed a correlation of r=0.49, confirming using an oblique rotation in the analysis. The factor loadings from the EFA are presented in Table 7.2.

7.2.3 Factor Interpretation

The final step in conducting the EFA involves interpreting and naming the factors. The analysis showed that the design principles of compactness, invisibility, and comfort loaded jointly on one factor, while the design principles of ease of connection, safety, and accuracy loaded jointly on another factor.

One may argue that the three principles of comfort, compactness, and invisibility, jointly contribute to deciding how easy it is to wear a device. The principles of compactness and invisibility share the common characteristic of wearability. That is, the smaller a device is, the easier it is to wear and conceal the device from the public. Compactness and comfort also share a common characteristic of wearability, as larger wearable devices may add more strain on a person making them less comfortable. A device that is simultaneously small and lightweight, easy to conceal from the public, and comfortable to wear may minimize inconvenience, aid users' comfort, and ultimately users' device acceptance. Considering the shared characteristics between the design principles of comfort, compactness, and invisibility this factor was labeled wearability. The design principles of ease of (blood)connection, safety, and accuracy are crucial aspects of blood-related medical procedures. These principles help ensure reliable medical procedures that aid patient's well-being. Considering these shared

aspects, this factor was labeled reliability.

Table 7.1: Exploratory factor analysis results. First round.

HF Design Principle	Factor 1	Factor 2
Ease of use	**0.38**	**0.43**
Compactness	**0.65**	0.13
Invisibility	**0.73**	-0.13
Comfort	**0.50**	0.11
Ease of connection	-0.07	**0.72**
Accuracy	0.07	**0.55**
Safety	0.03	**0.57**
SS loadings	1.47	1.45
Proportion of variance explained	0.5	0.5

Table 7.2: Exploratory factor analysis results. Final round.

HF Design Principle	Factor 1	Factor 2
Compactness	**0.71**	0.08
Invisibility	**0.66**	-0.14
Comfort	**0.55**	0.11
Ease of connection	-0.04	**0.74**
Accuracy	0.10	**0.50**
Safety	0.08	**0.54**
SS loadings	1.31	1.16
Proportion of variance explained	0.53	0.47

7.3 Structural equation modeling

Structural equation modeling (SEM) was conducted to better understand the relationship among users' demographic characteristics, human factors design principles for wearable medical devices, and proposed designs of a wearable hemodialysis device.

7.3.1 Specification and Hypothesis

Three structural equation models were proposed to explore the relationship between users' characteristics, the latent variables of wearability and reliability, and five proposed designs of a wearable hemodialysis device. Figure 7.1 displays the proposed structural equation model framework. Model 1 explores the relationship between the users' role as either a patient, care partner, nurse, or nephrologist, the latent variables of wearability and reliability, and five proposed designs of a wearable hemodialysis device. Model 2 explores the relationship between users' age, the latent variables of wearability and reliability, and five proposed designs of a wearable hemodialysis device. Lastly, Model 3 explores the relationship between users' gender, as either a male or a female, the latent variables of wearability and reliability, and five proposed designs of a wearable hemodialysis device.

Each model comprises a measurement model that considers the latent variables in the model, along with hypothesized directed relationships between variables. Proposing a structural equation model requires developing a hypothesis regarding the relationships between the variables in the model. As suggested by the literature in section 2.3, users' age and gender have been found to be among the key factors that influence users' intentions to adopt wearable medical devices. Also, studies show that the user role, particularly clinicians, influences device adoption.

In addition to the literature, the results from EFA in the preceding section provided a foundational understanding regarding the underlying relationships among the chosen human factors design principles. The results showed that six of the seven proposed design principles loaded on two latent variables. Comfort, compactness, and invisibility jointly loaded on one latent variable labeled wearability while accuracy, ease of connection, and safety jointly loaded on another latent variable labeled reliability. Studies suggest that the reliability of a

wearable hemodialysis device is affected by wearable attributes. For example, Dudarev and colleagues (2023) stated that measuring cardiac signals *"with a wearable sensor is similar to trying to measure one's weight while dancing on the scale"* and concluded that reliability varies based on the dynamic wearability during users' activities [48] Also, Fotadis and colleagues (2006) stated the total size and weight of a wearable system affects device reliability and should therefore be kept as low as possible [64]. Taking into account existing literature and prior findings, fifteen hypotheses were constructed. To be noted is that each constructed hypothesis is focused on the alternative option in the traditional hypothesis framework. That is, a supporting conclusion to a hypothesis indicates that a difference has been observed between the variables in the model.

Table 7.3: Hypothesized relationships between users' demographics, human factors design principles, and proposed designs of a wearable hemodialysis device.

Hypothesis	Hypothesized relationship
H1	Users' role affects wearability importance
H2	Users' role affects reliability importance
H3	Users' role affects design type preferences
H4	Users' age affects wearability importance
H5	Users' age affects reliability importance
H6	Users' age affects design type preferences
H7	Users' gender affects wearability importance
H8	Users' gender affects reliability importance
H9	Users' gender affects design type preferences
H10	Wearability affects reliability
H11	Wearability importance affects design type preferences
H12	Reliability importance affects design types
H13	Wearability mediates the relationship between users' demographic factors and design type preferences

Table 7.3 continued from previous page

Hypothesis	Hypothesized relationship
H14	Reliability mediates the relationship between users' demographic factors and design type preferences
H15	Wearability mediates the relationship between users' demographic factors and reliability importance

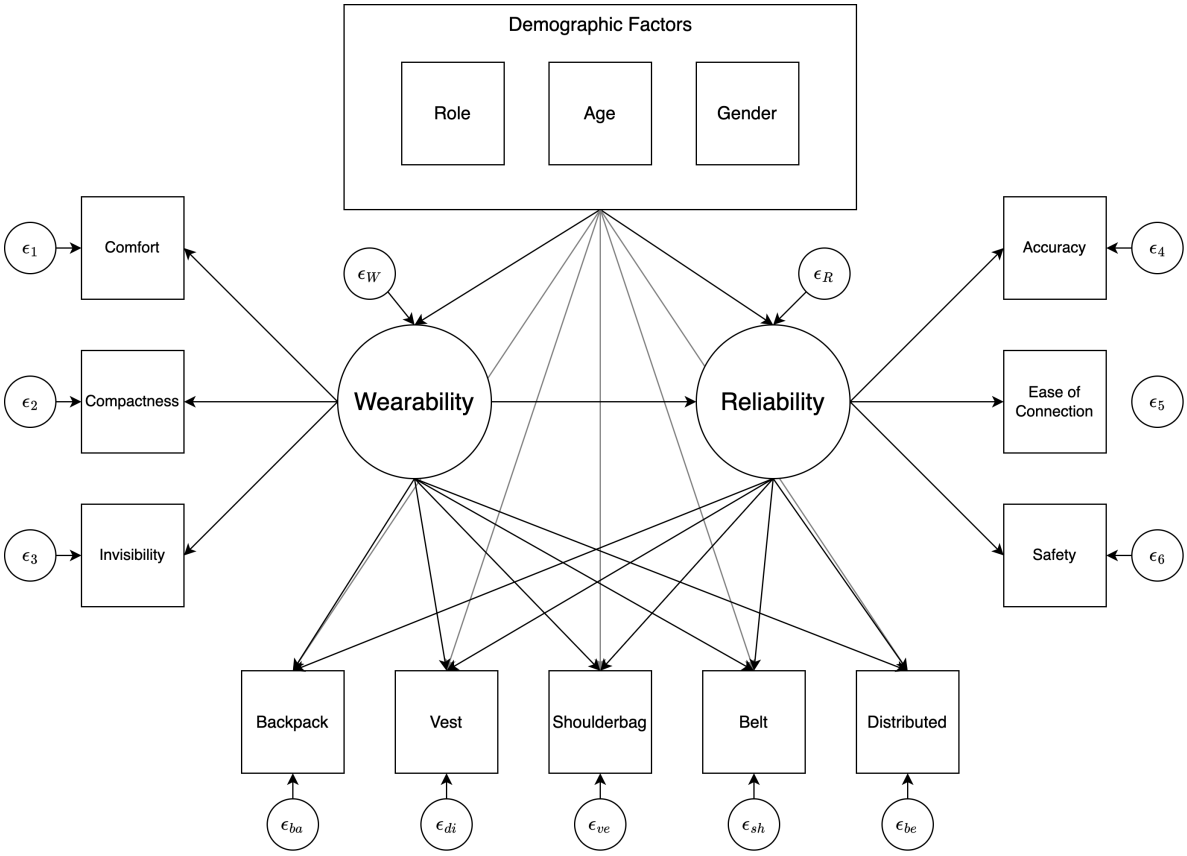

Figure 7.1: Hypothesized structural equation model. Path parameters and the correlations between all design types are omitted for ease of viewing.

7.3.2 Validation and Identification

The measurement model, displayed in Figure 7.2, was validated by assessing the unidimensionality, validity, and reliability of the model.

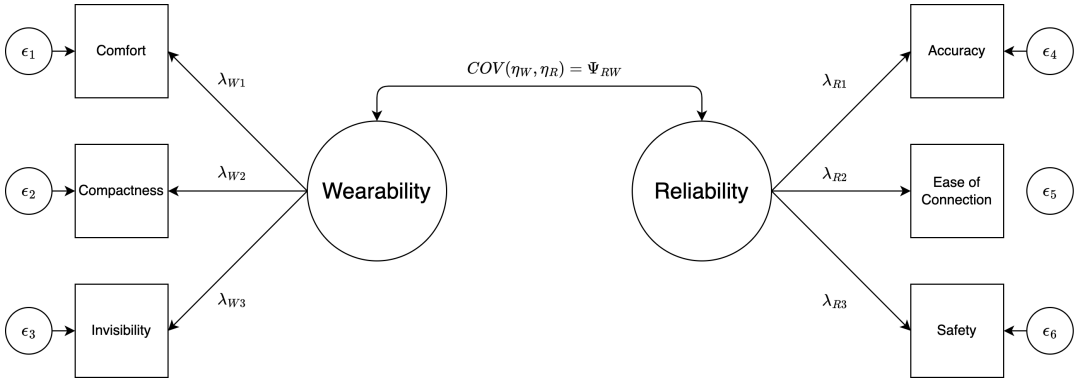

Figure 7.2: The measurement model.

Validation results are presented in Table 7.4. Given that all of the variables had standardized loadings of at least 0.5 on a latent variable, it was determined that unidimensionality had been attained. All variables in the model were statistically significant and no correlations between the measured independent variables exceeded 0.85 (Tables 9.2 and 9.1 in Appendix A). Examination of fit indices for the measurement model indicated a good model fit (χ^2= 3.975, df = 8, p = 0.859, TLI = 1.094, CFI = 1.0, RMSEA =0.0, (90% CI = [0.0, 0.049]), SRMR = 0.034). As a result, it was determined that validity had been attained. Lastly, although the average variance extracted, or the percentage of variance explained by each latent variable was below 0.5, it was determined that reliability had been attained given the composite reliability values being greater than 0.6.

Table 7.4: Factor validity and reliability scores.
CR = composite reliability, AVE = average variance extracted.

Latent Variables	Indicator Variables	Loadings	CR	AVE
Wearability	Compactness	0.78	0.683	0.429
	Comfort	0.615		
	Invisibility	0.541		
Reliability	Ease of connection	0.752	0.663	0.409
	Safety	0.606		
	Accuracy	0.567		

Before the structural equation model presented in Figure 7.1, was evaluated, it was ensured the model was identified. The model was identified both through visual inspection using the two-step rule and confirmed to be identified by R statistical software during analysis. Consistent with the two-step identification, at least two measured variables loaded on each latent variable. Also, upon tracing the paths in the model, the model was confirmed to be recursive, with no observable loops. Given the model met the identification criteria, it was concluded that unique estimates could be derived for each parameter in the model.

7.3.3 Data Preparation

To ensure a linear relationship between model variables, recategorization in the form of dummy coding was performed. The demographic factors of role and gender were converted into a series of dichotomous variables [194]. When dealing with more than two unordered categorical variables, the analyst needs to decide which category should serve as the baseline category to be used as a comparison category. Considering the role of nephrologists in recommending specific treatment modalities to patients, nephrologists were chosen as a baseline category. As a result, the users' role was coded as 0 if the participants were nephrologists, and coded as 1 if the participants were either patients, care partners, or nephrology nurses.

This choice allowed for direct comparison between patients and nephrologists. Users' gender was categorized based on users' demographic information. Given those results, users' gender was converted into a binary category with females coded as 1 and males coded as 0.

7.3.4 Estimation and Interpretation

User Role

Model 1, presented in Figure 7.3 explored the relationship among users' roles, the latent variables of wearability and reliability, and five proposed design types of a wearable hemodialysis device; a backpack design, a vest, a shoulderbag, a belt, and a distributed design.

The results from the structural equation model indicated a good model fit ($\chi^2 = 38.475$ df = 42, $p = 0.627$, TLI = 1.043, CFI = 1.000, RMSEA = 0.000 (95% CI: [0, 0.062]), SRMR = 0.047). The results showed a significant effect of the user role on wearability, where a significant difference was found between patients and nephrologists, and care partners and nephrologists on wearability with both patients and care partners having higher importance ratings for wearability compared to the nephrologists ($z = 3.920$, $p < 0.001$ and $z = 3.362$, $p < 0.01$, respectively). The results also showed a significant effect of role on reliability, where a significant difference was found between the nurses and nephrologists with nurses having higher importance ratings for reliability compared to the nephrologists ($z = 2.147$,$p < 0.05$).

Examining the relationship between the human factors design principles and design preferences, the results show that wearability significantly and positively influences importance ratings for reliability ($z = 2.213$, $p < 0.05$). Also, wearability significantly and positively influences preferences for the vest and the shoulder bag design ($z = 2.270$, $p < 0.05$ and $z = 2.502$, $p < 0.05$), whereas reliability significantly and positively influences the preferences for the distributed design ($z = 2.232$, $p < 0.05$). Additionally, the results show a significant direct effect of user role on the preferences for the shoulder bag design, where patients preferred the shoulder bag design significantly less compared to the nephrologists ($z = -3.137$, $p < 0.01$). The full model regression weights and test results are presented in Table 7.5 as supplementary materials.

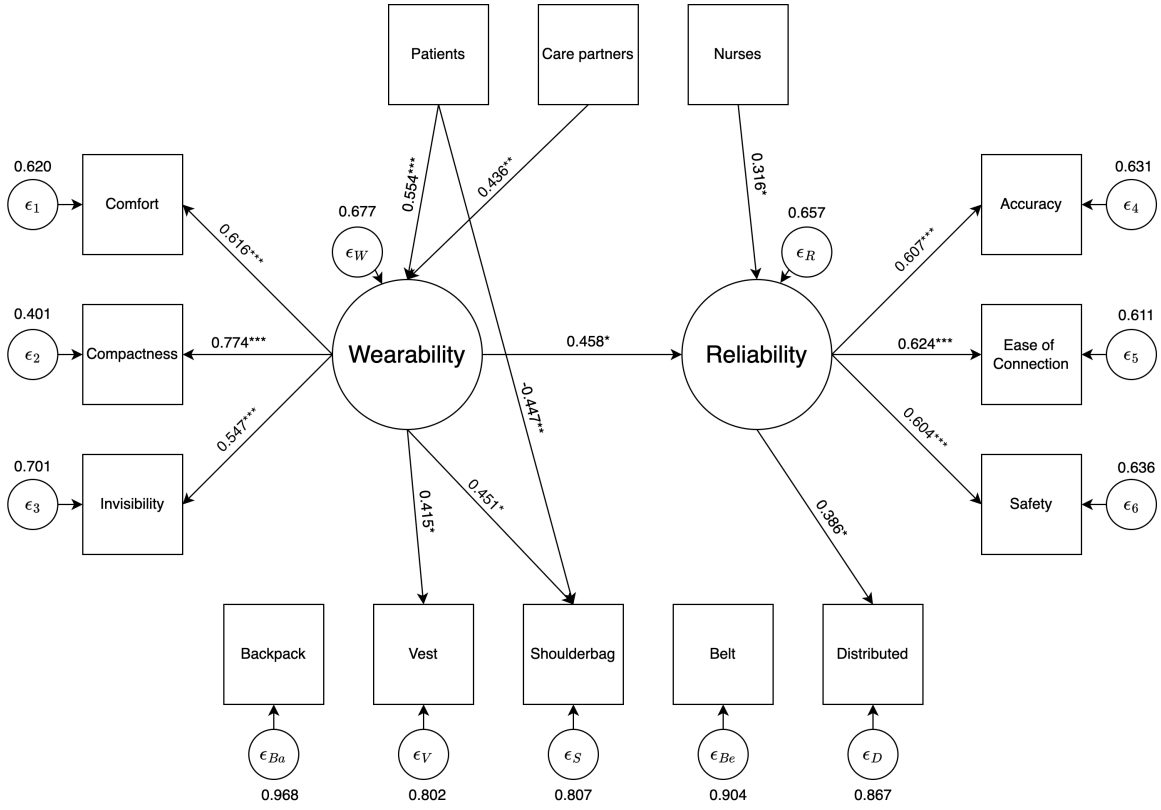

Figure 7.3: Structural equation model examining the relationship between user role, human factors design principles, and proposed design types of a wearable hemodialysis device. The coefficients displayed are the standardized estimates. Correlations between design types are omitted for ease of viewing. Nephrologists are the baseline comparison for user roles.

Exploring the mediating effects of the human factors principles, a significant mediating effect was found between the user role as a patient on reliability mediated by wearability ($z = 2.981$, $p < 0.01$). Also, a significant mediating effect was found between the user role as a patient and the shoulder bag design mediated by wearability ($z = 2.108$, $p < 0.05$). Marginal mediating effects of wearability were also observed; between the user's role as a patient and the vest design ($z = 1.964$ $p = 0.5$), between the users' role as a care partner and the shoulder bag and vest designs ($z = 1.881$, $p = 0.6$ and $z = 1.881$, $p = 0.6$, respectively). Additionally, marginal mediating effects were observed between the user's role as a care

partner and reliability mediated by wearability ($z = 1.900$, $p = 0.057$).

Table 7.5: Model 1, exploring the relationships between users' roles, human factors design principles, and designs of a wearable hemodialysis device (Nephrologists coded as 1 as the baseline comparison group, patients, care partners, and nurses coded as 0).

Relationship	Est.	SE	p val.	Std. est.	Partially std. est.	Conclusion
H1: Users' role as a patient affects wearability importance						
	1.633	0.416	0.000	0.554	1.344	Supported
H2: Users' role as a patient affects reliability importance						
	0.620	0.504	0.218	0.207	0.502	Not supported
H3: Users' role as a patient affects preferences for backpack design						
	-0.168	0.791	0.832	-0.026	-0.064	Not supported
H3: Users' role as a patient affects preferences for belt design						
	-1.061	0.850	0.212	-0.182	-0.442	Not supported
H3: Users' role as a patient affects preferences for shoulder bag design						
	-2.888	0.921	0.002	-0.447	-1.085	Supported
H3: Users' role as a patient affects preferences for vest design						
	-0.093	0.844	0.912	-0.016	-0.038	Not supported
H3: Users' role as a patient affects preferences for distributed design						
	-0.168	0.791	0.832	-0.025	-0.061	Not supported
H1: Users' role as a care partner affects wearability importance						
	1.701	0.506	0.001	0.436	1.400	Supported
H2: Users' role as a care partner affects reliability importance						
	0.245	0.599	0.682	0.062	0.199	Not supported
H3: Users' role as a care partner affects preferences for backpack design						
	0.960	0.930	0.302	0.114	0.367	Not supported
H3: Users' role as a care partner affects preferences for belt design						
	-0.975	0.999	0.329	-0.126	-0.406	Not supported

Table 7.5 continued from previous page

Relationship	Est.	SE	p val.	Std. est.	Partially std. est.	Conclusion
H3: Users' role as a care partner affects preferences for shoulder bag design						
	-1.898	1.083	0.080	-0.222	-0.713	Not supported
H3: Users' role as a care partner affects preferences for vest design						
	1.331	0.994	0.181	0.170	0.546	Not supported
H3: Users' role as a care partner affects preferences for distributed design						
	0.960	0.930	0.302	0.109	0.350	Not supported
H1: Users' role as a nurse affects wearability importance						
	0.472	0.325	0.147	0.185	0.388	Not supported
H2: Users' role as a nurse affects reliability importance						
	0.819	0.382	0.032	0.316	0.664	Supported
H3: Users' role as a nurse affects preferences for backpack design						
	-0.501	0.706	0.478	-0.091	-0.191	Not supported
H3: Users' role as a nurse affects preferences for belt design						
	-0.544	0.663	0.412	-0.108	-0.227	Not supported
H3: Users' role as a nurse affects preferences for shoulder bag design						
	-0.121	0.712	0.865	-0.022	-0.045	Not supported
H3: Users' role as a nurse affects preferences for vest design						
	-0.169	0.657	0.797	-0.033	-0.069	Not supported
H3: Users' role as a nurse affects preferences for distributed design						
	-1.291	0.731	0.077	-0.225	-0.472	Not supported
H10: Wearability affects reliability						
	0.465	0.210	0.027	0.458	0.458	Supported
H11: Wearability affects preferences for backpack design						
	-0.330	0.395	0.404	-0.153		Not supported
H11: Wearability affects preferences for belt design						
	0.576	0.366	0.115	0.292		Not supported
H11: Wearability affects preferences for shoulder bag design						

Table 7.5 continued from previous page

Relationship	Est.	SE	p val.	Std. est.	Partially std. est.	Conclusion
	0.988	0.395	0.012	0.451		Supported
H11: Wearability affects preferences for vest design						
	0.834	0.367	0.023	0.415		Supported
H11: Wearability affects preferences for distributed design						
	-0.491	0.413	0.234	-0.218		Not supported
H12: Reliability affects preferences for backpack design						
	0.249	0.378	0.511	0.117		Not supported
H12: Reliability affects preferences for belt design						
	0.247	0.344	0.474	0.127		Not supported
H12: Reliability affects preferences for shoulder bag design						
	0.035	0.371	0.925	0.016		Not supported
H12: Reliability affects preferences for vest design						
	-0.435	0.334	0.194	-0.220		Not supported
H12: Reliability affects preferences for distributed design						
	0.858	0.384	0.026	0.386		Supported

User Age

Model 2, shown in Figure 7.4, explored the relationship between users' age, the latent variables of wearability and reliability, and the five proposed design types.

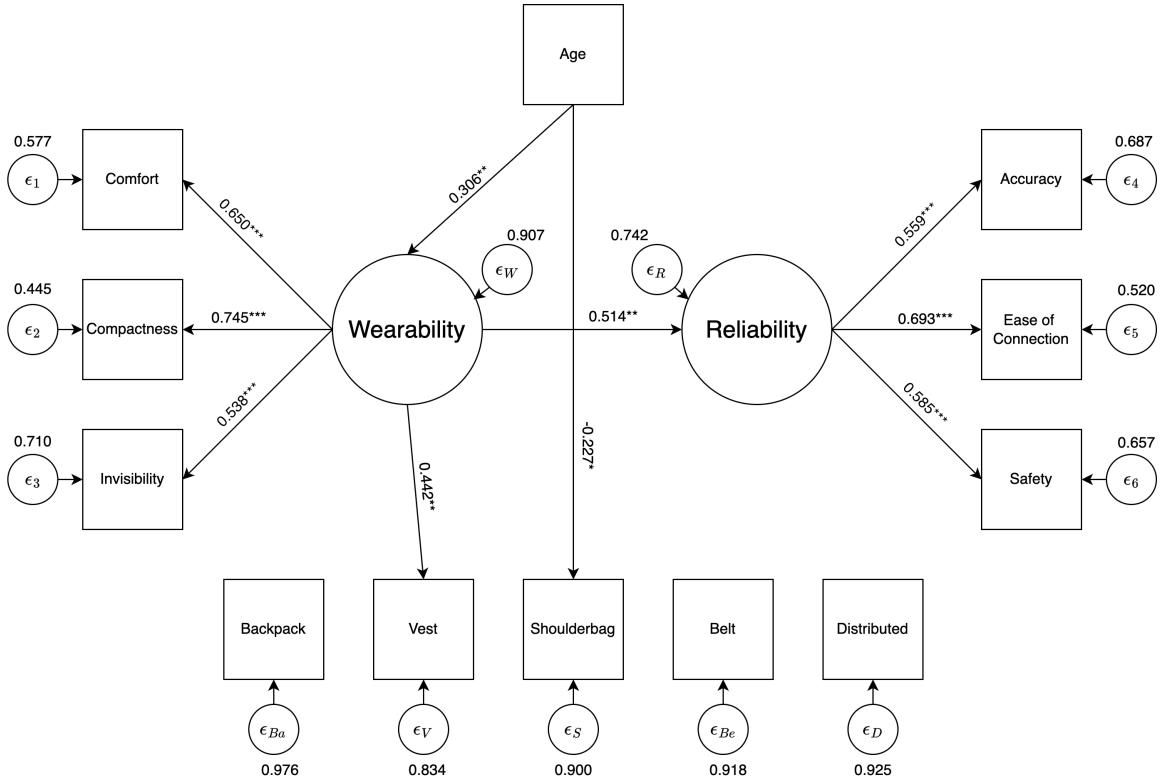

Figure 7.4: Structural equation model examining the relationship among users' age, human factors design principles, and proposed design types of a wearable hemodialysis device. The coefficients displayed are the standardized estimates. Correlations between design types are omitted for ease of viewing. Nephrologists are the baseline comparison for user roles.

The results indicated a good model fit ($\chi^2 = 27.457$, df = 32, $p = 0.696$, TLI = 1.066, CFI = 1.000, RMSEA = 0.000 (95% CI: [0, 0.061]), SRMR = 0.047). The results showed a significant positive effect of age on wearability ($z = 2.449$, $p < 0.05$), a significant positive effect of wearability on reliability ($z = 2.761$, $p < 0.01$), a significant positive effect of wearability on preferences for the vest design ($z = 2.644$, $p < 0.01$), and a significant negative

direct effect of age on preferences for the shoulder bag design (z = -2.092, p <0.5). Marginal mediating effects were found between age and preferences for the vest design through wearability (z = 1.808, p =0.07) and between age and reliability mediated by wearability (z = 1.848, p =0.065). The model regression weights and hypothesis test results are presented in Table 7.6 as supplementary material.

Table 7.6: Model 2, exploring the relationships between users' age, human factors design principles, and designs of a wearable hemodialysis device.

Relationship	Est.	SE	p val.	St. est.	Conclusion
H4: Users' age affects wearability importance					
	0.029	0.012	0.014	0.306	Supported
H5: Users' age affects reliability importance					
	-0.002	0.014	0.873	-0.021	Not supported
H6: Users' age affects preferences for backpack design					
	-0.021	0.027	0.439	-0.086	Not supported
H6: Users' age affects preferences for belt design					
	0.009	0.024	0.708	0.041	Not supported
H6: Users' age affects preferences for shoulder bag design					
	-0.055	0.026	0.036	-0.227	Supported
H6: Users' age affects preferences for vest design					
	0.017	0.024	0.488	0.076	Not supported
H6: Users' age affects preferences for distributed design					
	0.019	0.028	0.498	0.075	Not supported
H10: Wearability affects reliability					
	0.568	0.206	0.006	0.514	Accepted
H11: Wearability affects preferences for backpack design					
	-0.264	0.419	0.528	-0.106	Not supported
H11: Wearability affects preferences for belt design					
	0.458	0.373	0.220	0.200	Not supported

Table 7.6 continued from previous page

Relationship	Est.	SE	p val.	St. est.	Conclusion
H11: Wearability affects preferences for shoulder bag design					
	0.708	0.413	0.087	0.744	Not supported
H11: Wearability affects preferences for vest design					
	1.025	0.388	0.008	0.442	Supported
H11: Wearability affects preferences for distributed design					
	-0.411	0.440	0.350	-0.158	Not supported
H12: Reliability affects preferences for backpack design					
	0.294	0.370	0.426	0.130	Not supported
H12: Reliability affects preferences for belt design					
	0.226	0.333	0.498	0.109	Not supported
H12: Reliability affects preferences for shoulder bag design					
	0.082	0.368	0.823	0.036	Not supported
H12: Reliability affects preferences for vest design					
	-0.492	0.334	0.140	-0.235	Not supported
H12: Reliability affects preferences for distributed design					
	0.725	0.382	0.058	0.307	Not supported

User Gender

The results from the structural equation model exploring the relationship among gender, human factors design principles, and design types indicated an acceptable model fit (Chi2 = 33.666 df = 32, $p = 0.387$, TLI = 0.987, CFI = 0.989, RMSEA = 0.024 (95% CI: [0, 0.082]), SRMR = 0.049).

The results show a significant positive effect of gender on preferences for the shoulder bag design ($z = 2.815$, $p < 0.01$) where females prefer the shoulder bag design more than males. The results also show a significant positive effect of wearability on reliability ($z = 2.871$, $p < 0.01$), a significant positive effect of wearability on preferences for the vest

design ($z = 2.920$, $p < 0.01$), and a significant positive effect of reliability on the preferences for the distributed design ($z = 2.009$, $p < 0.05$). No significant effects were found between gender and wearability or gender and reliability. No significant mediating effect was found between wearability and preferences of the distributed design through Reliability. The model regression weights and hypothesis test results are presented in Table 7.7 as supplementary material.

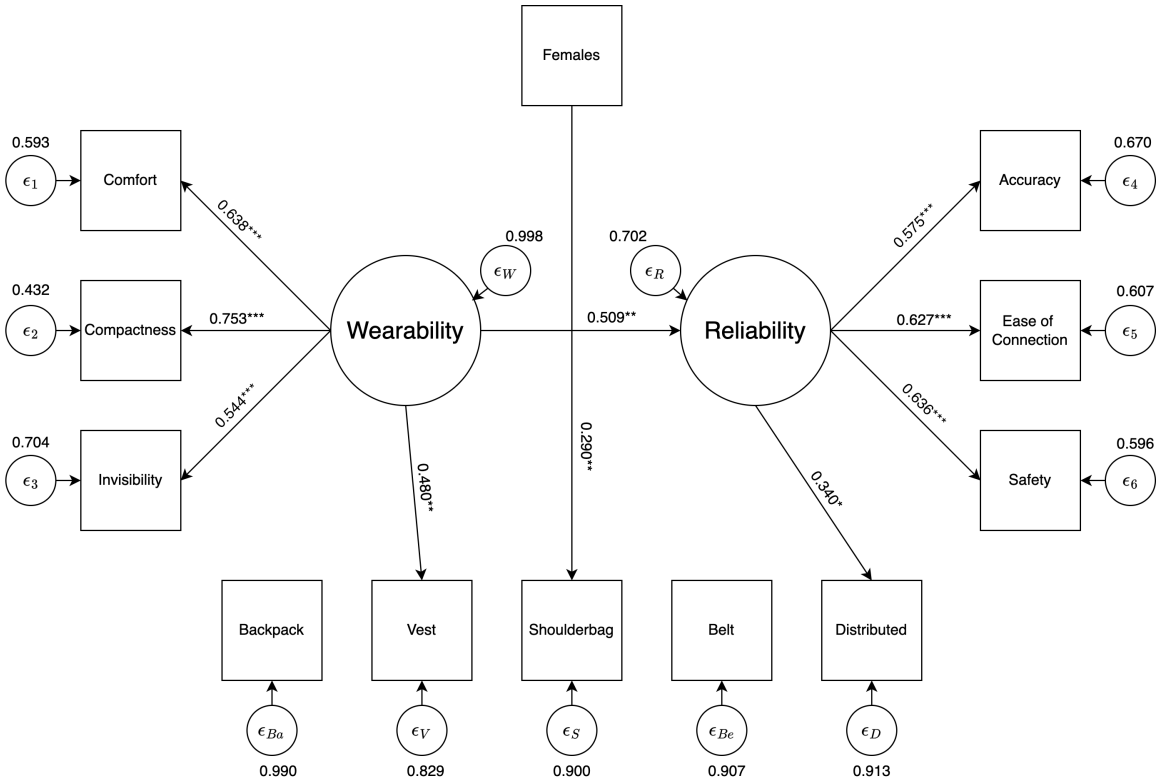

Figure 7.5: Structural equation model examining the relationship between users' gender, human factors design principles, and proposed design types of a wearable hemodialysis device. The coefficients displayed are the standardized estimates. Correlations between design types are omitted for ease of viewing. Nephrologists are the baseline comparison for user roles.

Table 7.7: Model 3, exploring the relationship between users' gender, human factors design principles, and proposed designs of a wearable hemodialysis device (Males are coded as 1 as the baseline comparison group, females are coded as 0).

Relationship	Est.	SE	p val.	Std. est.	Partially std. est.	Conclusion
H7: Users' gender affects wearability importance						
	0.084	0.248	0.735	0.042	0.084	Not supported
H8: Users' gender affects reliability importance						
	0.422	0.297	0.155	0.177	0.354	Not supported
H9: Users' gender affects preferences for backpack design						
	-0.159	0.569	0.779	-0.030	-0.061	Not supported
H9: Users' gender affects preferences for belt design						
	-0.607	0.504	0.228	-0.126	-0.253	Not supported
H9: Users' gender affects preferences for shoulder bag design						
	1.544	0.548	0.005	0.290	0.580	Supported
H9: Users' gender affects preferences for vest design						
	0.423	0.521	0.417	0.087	0.173	Not supported
H9: Users' gender affects preferences for distributed design						
	-0.701	0.592	0.236	-0.128	-0.256	Not supported
H10 Wearability affects reliability						
	0.607	0.211	0.004	0.509		Supported
H11: Wearability affects preferences for backpack design						
	-0.288	0.427	0.501	-0.110		Not supported
H11: Wearability affects preferences for belt design						
	0.492	0.377	0.192	0.205		Not supported
H11: Wearability affects preferences for shoulderbag design						
	0.668	0.413	0.106	0.251		Not supported
H11: Wearability affects preferences for vest design						

Table 7.7 continued from previous page

Relationship	Est.	SE	p val.	Std. est.	Partially std. est.	Conclusion
	1.170	0.401	0.004	0.480		Supported
H11: Wearability affects preferences for distributed design						
	-0.403	0.448	0.368	-0.148		Not supported
H12: Reliability affects preferences for backpack design						
	0.211	0.380	0.578	0.096		Not supported
H12: Reliability affects preferences for belt design						
	0.257	0.338	0.447	0.128		Not supported
H12: Reliability affects preferences for shoulder bag design						
	-0.167	0.366	0.649	-0.075		Not supported
H12: Reliability affects preferences for vest design						
	-0.542	0.343	0.114	-0.265		Not supported
H12: Reliability affects preferences for distributed design						
	0.781	0.389	0.045	0.340		Supported

Hypothesis Conclusions

This study proposed three structural equation models to explore the relationship between users' demographic characteristics, selected human factors design principles, and proposed designs of a wearable hemodialysis device. The human factors design principles were selected based on existing literature on designing wearable medical devices. Through exploratory factor analysis, two underlying structures of the human factors design principles were identified. The principles of comfort, compactness, and invisibility jointly formed one latent variable labeled wearability, while the principles of accuracy, ease of connection, and safety jointly formed the second latent variable labeled reliability.

Fifteen hypotheses were formed to explore the relationship between users' demographic characteristics, the latent variables representing the human factors design principles, and five proposed designs of a wearable hemodialysis device.

The results from this study show that users' specific roles influence importance ratings of human factors principles for both wearability and reliability. A significant effect of the user's role as either a patient or a care partner compared to nephrologists was found on the importance of wearability. Also, a significant effect of the user's role as a nurse, compared to nephrologists, was found on the importance of reliability. The results also showed a significant effect of users' role on design type preferences with patients showing less preference for the the shoulder bag design compared to the nephrologists. The results also show that users' age significantly influences wearability with older people placing greater importance on ensuring the wearability of a hemodialysis device. Users' age also significantly influences design preferences with younger people showing a greater preference for the shoulder bag design. However, no significant influence was found of users' age on ensuring the reliability of the device. Exploring the effect of gender, the findings show that gender significantly influences design preferences with females preferring the shoulder bag designs more than males. No significant effect of gender was found on the wearability or reliability of the device.

This study also explored the influence of wearability on reliability and the direct and mediating effects of these variables on design type preferences. For all three models, a significant effect of the wearability design principles was found on the reliability design principles. Also, both wearability and reliability were found to significantly influence design type preferences for the shoulder bag, vest, and distributed designs. Wearability significantly and positively influenced preferences for the vest and shoulder bag designs, while reliability significantly and positively influenced the preferences for the distributed design. Exploring the mediating effects, a significant mediating effect of wearability was found between the users' role as a patient, compared to a nephrologist, on the shoulder bag design preferences. Also, a significant mediating effect of wearability was found between users' role as a patient, compared to a nephrologist, on reliability. All hypotheses conclusions are presented in Table 7.8 where the hypotheses were accepted when the significance level was less than 0.05.

Table 7.8: Conclusion summary of hypothesized relationships between users' demographics, human factors design principles, and proposed designs of a wearable hemodialysis device.

Hypothesis	Hypothesized relationship	Conclusion
H1	Users' role affects wearability importance	Supported
H2	Users' role affects reliability importance	Supported
H3	Users' role affects design type preferences	Supported
H4	Users' age affects wearability importance	Supported
H5	Users' age affects reliability importance	Not supported
H6	Users' age affects design type preferences	Supported
H7	Users' gender affects wearability importance	Not supported
H8	Users' gender affects reliability importance	Not supported
H9	Users' gender affects design type preferences	Supported
H10	Wearability affects reliability	Supported
H11	Wearability importance affects design type preferences	Supported
H12	Reliability importance affects design type preferences	Supported
H13	Wearability mediates the relationship between users' characteristics and design type preferences	Supported
H14	Reliability mediates the relationship between users' characteristics and design type preferences	Not supported
H15	Wearability mediates the relationship between users' characteristics and reliability importance	Supported

7.4 Discussion and Conclusions

This study combined exploratory factor analysis and structural equation modeling to explore the relationships between users' demographic characteristics, selected human factors design principles, and five proposed designs of a wearable hemodialysis device.

Through exploratory factor analysis, this study shows that seven selected prominent hu-

man factors design principles load on two factors. The principles of ensuring users' comfort, compactness, and invisibility of a device loading on one factor labeled wearability while safety, accuracy, and the ease of (blood)connections loaded on a second factor labeled reliability. Jointly, these human factors design principles not only help predict users' preferences for a particular design type of a wearable hemodialysis device but may also help explain the importance that users place on other human factors design principles. For example, a significant mediating effect of wearability was found between users' roles and the human factors design principles of reliability. These findings suggest that design aspects of ensuring the wearability of a hemodialysis device positively influence the reliability aspects of the device.

Interestingly, one of the most prominent human factors design principle of ensuring the ease of using the device was found to load on both wearability and reliability. Literature on best practices for exploratory factor analysis suggests that variables that load on more than one factor may be inefficient in measuring a single phenomenon [213]. Although the fundamental focus of human factors engineering is to ensure the ease of using a device [147], the findings from this study show that user's perception of the term 'ease of use' spans broad dimensions. This may also be due to a flaw in the data collection process where the term was not consistently described across populations; ease of use means simple to operate (primary study population) and ease of use means the device is easy and simple to use (clinicians study population). This realization indicates that 'ease of use' may be perceived in two distinct ways: how easy it may be to wear a device and how easy it may be to operate a device. Previous findings of exploring patients' and care partners' perspectives of their most ideal dialysis device (section: 4.2.2) showed preferences for a device that is simultaneously easy to use, easy to clean, easy to understand, and easy to wear supporting the terms' multi-dimensionality. Future studies should aim to delve deeper into the influence of the selected human factors principles, particularly across more diverse dimensions, encompassing physical, cognitive, and emotional aspects in greater detail [3].

The findings from this study have important practical implications. The findings provide researchers and developers of wearable hemodialysis devices with a better understanding of users' perspectives based on their demographic differences. Users' role, age, and gender all

helped predict users' preferences for the shoulder bag design with nephrologists, females, and younger users placing the greatest preferences on this particular design type. These findings support the results of previous studies showing that clinicians' perspectives ([149, 198]), age ([56, 69]), and gender ([69, 180]) influence device adoption of medical technology. These findings highlight the importance of exploring users' preferences based on their demographic traits and raise awareness of the fact that a single design type may not universally cater to the needs of diverse users.

In terms of wearability, patients, care partners, and older users were found to place greater importance on aspects of wearability compared to nephrologists and those of a younger age. Also, nephrology nurses were found to place greater importance on aspects of reliability compared to nephrologists. A speculated explanation for these findings considers users' proximity to a hemodialysis device. As the ultimate end-users of a wearable hemodialysis device, it is understandable that patients may place greater importance on design aspects that enhance their physical comfort while wearing a medical device. Considering the different roles of nephrologists and nephrology nurses, the nurses may interact more frequently with a hemodialysis device while nephrologists may be more focused on diagnosis, prescriptions, and disease progression. Future research is needed to understand the varied perspectives of clinicians regarding the reliability of a wearable hemodialysis device. In terms of design preferences, wearability was found to positively predict preferences for the shoulder bag and vest designs while reliability positively predicted preferences for the distributed design. These findings shed light on users' perceptions where users perceptions of the concepts of a vest and shoulder bag designs are influenced by aspects of wearability while users' perceptions of the concept of a distributed design are influenced by aspects of reliability.

This study has several limitations providing guidance for results interpretation and future research directions. First, this study is limited to the population size and geographical location of the study participants. Although studies have demonstrated the successful use of structural equation models with sample sizes as low as 50 participants [188], structural equation modeling is generally considered to be a statistical technique that requires large sample sizes [111]. Although full structural equation models with latent variables have the advantage of accounting for measurement errors that in return provide better parameter

estimates, studies have shown that models with low sample sizes may return biased results with under-estimated path coefficients [137]. In terms of the study participants, the majority of participants were located in the United States and were all of adult age. Considering these limitations, the findings from this study should be interpreted both in accordance with the low sample size and the study population.

A second limitation of this study relates to the validity of the models. As shown in Figures 7.3, 7.4, and 7.5, the models only account for limited variance in the dependent variables. The results show that users' role accounts for most of the variance explained in wearability (33%), users' role and wearability account for most of the explained variance in reliability (34.3%), users' role and wearability account for most of the explained variance in the preferences for the vest and shoulder bag designs (19.8% and 19.3%, respectively), and users' role, wearability, and reliability account for most of the explained variance in the preferences for the distributed design (13.3%). In that context, these models only present a part of a much larger picture. Additional variables need to be discovered to fully understand the relationship between users' demographic characteristics, human factors design principles for wearable medical devices, and users' preferences for a particular design of a wearable hemodialysis device.

The validity of the models can be further improved with revisions of the measurement instrument. Although the data passed adequacy tests for exploratory factor analysis, the reliability of the measurement instruments was only slightly higher than the recommended thresholds. This realization suggests that although the selected human factors design principles were found to measure two underlying constructs, each design principle may still exhibit unique characteristics in its design aspects. By incorporating a greater number of human factors design principles, for example, aspects of ergonomy and customization [147], social and physical design aspects [69], or dimensions of comfort including slippage, pulling on clothing, and restricting movement [112], a more comprehensive understanding of users' design preferences may be obtained.

Overall, the findings from this study show that users' demographic factors and human factors design principles help predict the design preferences of a wearable hemodialysis device. Users' roles had the most influence on the perceived importance of human factors design

principles for wearable medical devices, compared to users' age and gender. Furthermore, the human factors design principles not only influenced design type preferences but also influenced the perceived importance of other design principles. Ultimately, these findings offer researchers and developers of a wearable hemodialysis device a deeper understanding of how users' individual characteristics and design aspects influence design preferences.

Chapter 8

SUMMARY AND FINAL REMARKS

8.1 Study Objective

The objective of this dissertation is to provide a foundational understanding of users' needs for a wearable hemodialysis system using human factors engineering principles. As discussed in section 1, the overall goal of human factors engineering is to optimize the interaction between humans and systems. The foundational work in achieving this goal begins with understanding users' needs during the early stages of system design. Recent advances in treatment delivery for patients with kidney disease allow for a new generation of miniaturized and wearable hemodialysis devices. Such devices have the potential to drastically improve the lives of patients with kidney disease by allowing them near-continuous treatments that better replicate normal kidney functioning. For such a device to be successful, and accepted by patients and their clinical partners, it is important to understand the needs and perspectives of users. Doing so in the early design stages helps optimize the design process in line with users' needs. To provide a foundational understanding of users' needs for a wearable hemodialysis system, this dissertation considers four research objectives.

First, this dissertation explores patients' and care partners' needs and perspectives of a wearable hemodialysis system design (R1) along with their needs and expectations for associated monitoring and instructional procedures (R2). Complementing the first research objective, this dissertation also explores nephrologists' and nephrology nurses' perspectives on a wearable hemodialysis device (R3). Lastly, the relationship among users' demographic characteristics, human factors design principles, and proposed designs of a wearable hemodialysis device are explored (R4). The remaining part of this section reviews the main findings of each research objective, contributions, and limitations, and highlights future research directions.

8.2 Review of Findings

8.2.1 R1: What are Patients' and Care Partners' Needs and Perspectives of a Wearable Hemodialysis System?

The goal of this research was to characterize patients' and care partners' needs and perspectives of a wearable hemodialysis system. A total of 42 patients and 20 care partners completed a questionnaire and were subsequently interviewed either in person or virtually over a computer-based platform. Using a mixed approach of qualitative and quantitative analysis methods, the use specifications of a wearable hemodialysis device were characterized by looking at the limitations of current hemodialysis systems (section 4.1.1), potential use environments, and concerns (sections 4.1.2, 4.1.3, 4.1.4), and use scenarios (section 4.1.2). Then, patients' and care partners' perspectives on two main components of a wearable hemodialysis system were characterized, a wearable hemodialysis device (section 4.2) and a vascular connection device (section 4.3). For both devices, the users' described ideal design forms (section 4.2.1 and 4.3.1), ideal features of the devices (sections 4.2.2 and 4.3.2), and potential challenges that may arise when using the devices (sections 4.2.3 and 4.3.3).

Exploring patients' and care partners' experiences with current hemodialysis treatments the findings show that current procedures negatively affect patients' physical and mental states. Current treatment procedures require patients to spend multiple hours several times a week tethered to a hemodialysis device. As a result, patients report experiencing physical challenges due to immobility during treatment, being uncomfortable, and unable to use a restroom. Both patients and care partners also reported experiencing mental challenges including frustration, stress, depression, fear, and anger. An overlap between mental and physical challenges was also observed where patients reported fearing pain due to frequent needle sticks for blood access.

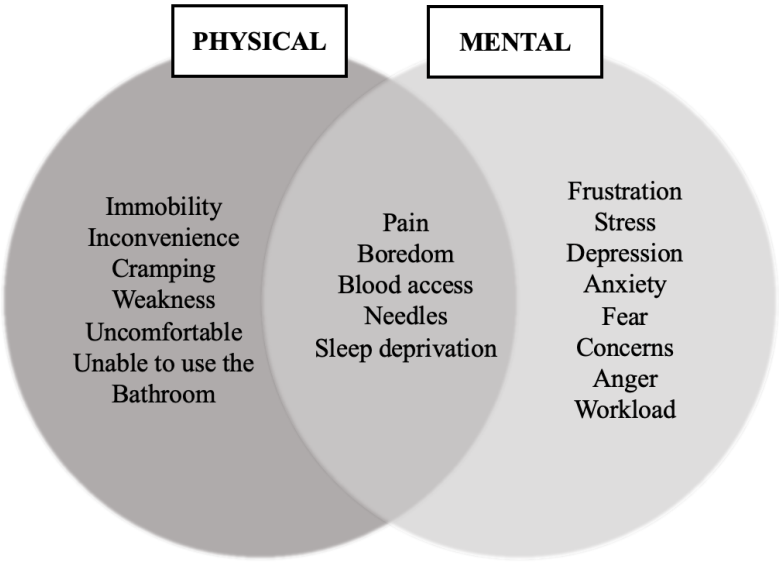

Figure 8.1: Summary of the physical and mental challenges patients and care partners experience in relation to current hemodialysis treatments (Primary study population).

The patients and care partners also described their envisioned use environment of the system and use scenarios. Although some patients do not long to dialyze in public places such as at their respective work offices or in a public park, the findings show that most patients want to be able to use a wearable hemodialysis device in diverse places. They long to be able to dialyze while doing everyday activities inside and around their homes, while traveling, exercising, and while attending social events. Table 8.1 presents the key summary of use environments, use scenarios and concerns about using a wearable hemodialysis device.

Table 8.1: Summary of use environments, use scenarios, and travel concerns in relation to using a wearable hemodialysis device (Primary study population).

Activities	Use scenarios	Use environment	Not willing to dialyze	Current concerns
Everyday	Working, Yardwork, Cooking, Household, Eating, Showering, Walking, Driving, Washing the car, Grocery shopping	Home, Work office	Work office	
Travel	Vacation, Visit family, Visit friends, Escape, Relax, Outdoor recreation, Natural attractions, Business trips,	Hotel, Airport, Airplane,	Car, Camping, Tent, Public park	Dialysis, Scheduling dialysis, Access to dialysis, Trust in treatment elsewhere. Time between treatments, Physical abilities, Needing medication
Physical	Exercise, Move around, Golfing, Play baseball, Bowling, Climbing, Skating, Walking,	Walking, Hiking	Gym	
Social	Shopping, Family time, Football games, Meet co-workers, Meet friends, Movies, Restaurants	Friend's house, Event, Show, Party, Restaurants	Shopping	

Table 8.1 continued from previous page

Activities	Use scenarios	Use environment	Not willing to dialyze	Current concerns
Leisure	Fishing, Listen to music, Play music, Read			
Other	Anything, Everything, Be normal	Doctors' office, Dentist		

The patients and care partners in this study were also asked to name features of their ideal hemodialysis device. As shown in Figure 8.2 patients and care partners share many of the same perspectives mentioning a particular ideal location to wear the device, longing for a device with different treatment timing options, a compact, safe, and durable device. The findings also detected unique perspectives where patients long for a device that they can independently use and is comfortable to wear while care partners talked more about ensuring the efficiency and quality of the device.

This research also explored patients' and care partners' perspectives on potential challenges related to a wearable hemodialysis device. As shown in Figure 8.3, patients and care partners have both unique and shared perspectives. Also, and interestingly, many of the ideal features they long for in a wearable hemodialysis device become potential challenges if not met in design. For example, safety, ease of use, mobility, and compactness were all shared perspectives of ideal features and potential challenges. Potential challenges unique to patients' perspectives included ensuring their comfort, gaining blood access, and ensuring treatment compliance. The patients were also concerned about the device being too complicated for older patients. Unique to care partners' perspectives included their concern regarding the lack of monitoring patients' treatments, how to clean the device between treatments, and gaining trust in the device.

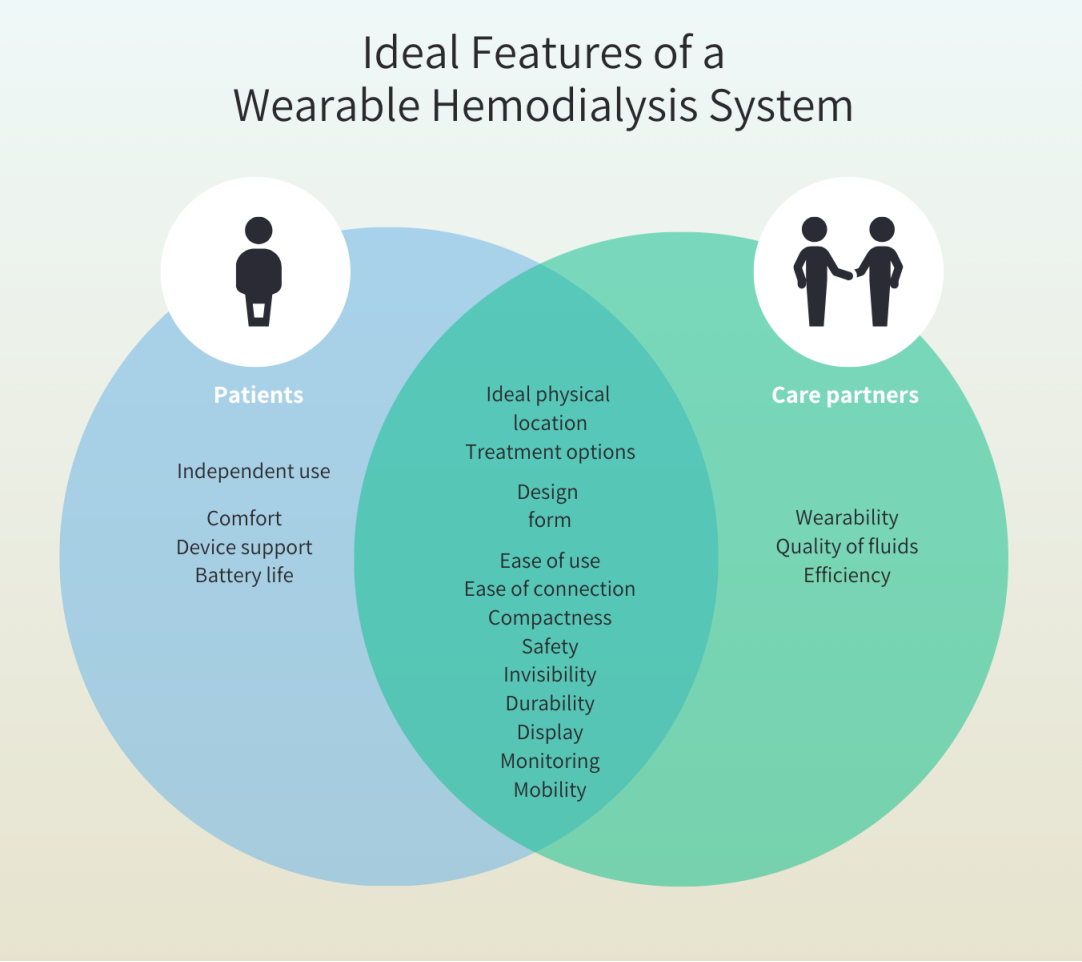

Figure 8.2: Summary of ideal features of a wearable hemodialysis device (Primary study population).

Ensuring a safe and user-friendly way for patients to gain access to their bloodstream is a critical prerequisite for the success of a wearable hemodialysis device. A vascular connection device aims to allow a patient to make a connection and disconnection between the wearable hemodialysis device and their bloodstream. Analysis of participants' perspectives shows that most participants would be willing to allocate five minutes, once or twice a day, to make a blood connection. They also expressed a preference for placing a catheter on the chest area and carrying a vascular connection device, that is no larger than a smartphone or heavier than 0.2 kg, either in a pocket on the upper torso or around the waist area.

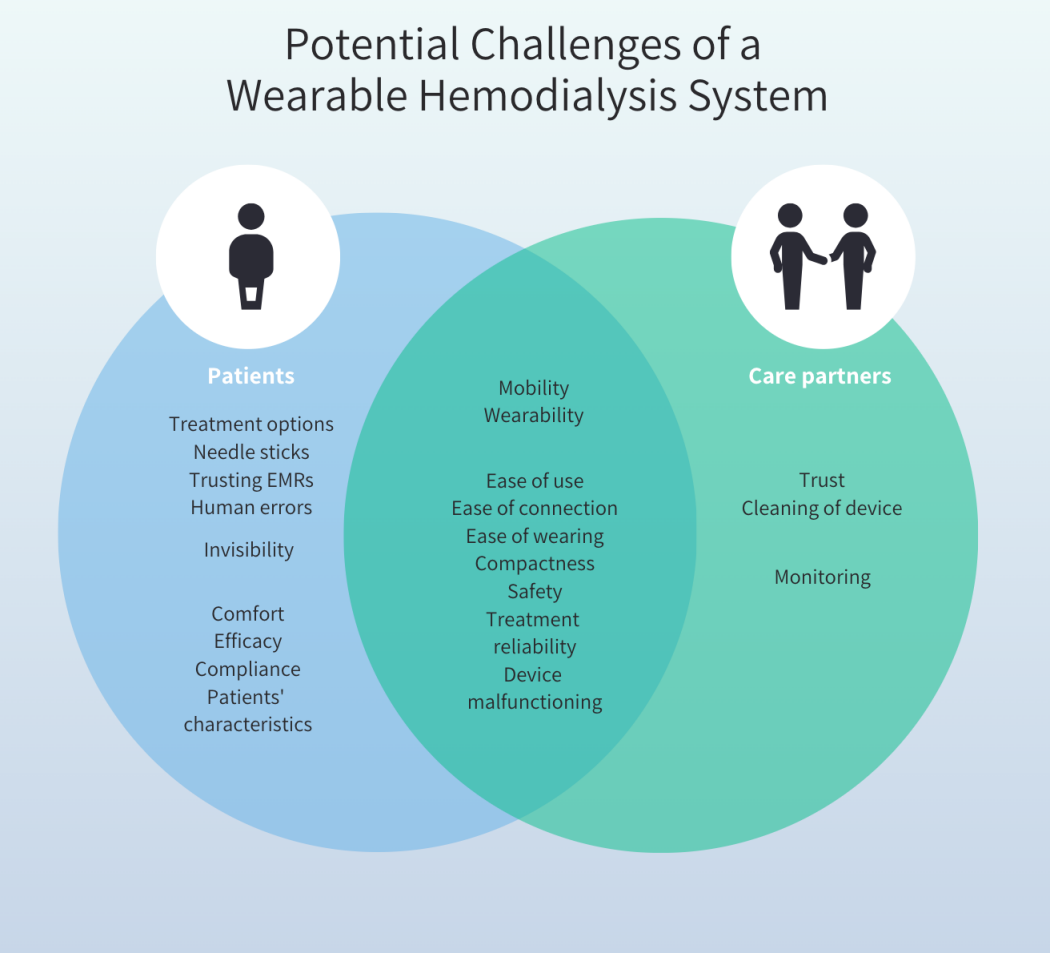

Figure 8.3: Summary of potential challenges of a wearable hemodialysis device (Primary study population).

The participants were also asked to name the ideal features of a vascular connection device and express their concerns related to its use. As shown in Figures 8.4 and 8.5, patients and care partners share many of the same perspectives and many of the ideal features and challenges previously identified for the wearable hemodialysis device were also identified for a vascular connection device. However, while the patients and care partners were generally more concerned with the ease of use, compactness, and malfunctioning of the wearable hemodialysis device, their concerns shifted towards the risk of infection, bleeding, and patients' self-consciousness when asked about a vascular connection device.

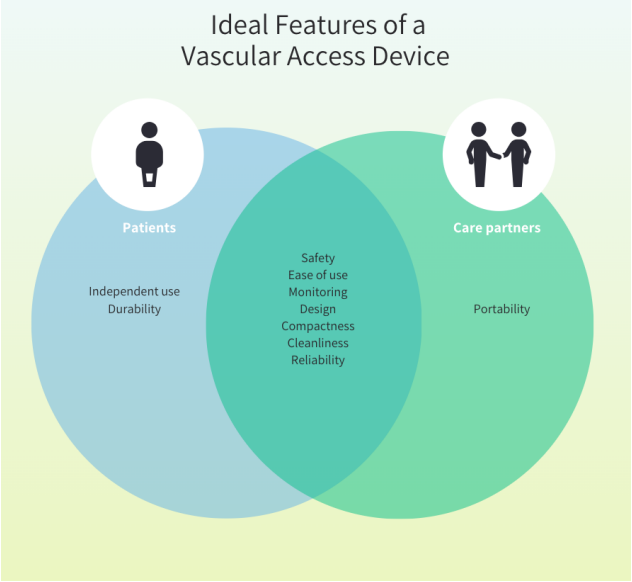

Figure 8.4: Summary of ideal features of a vascular connection device (Secondary study population).

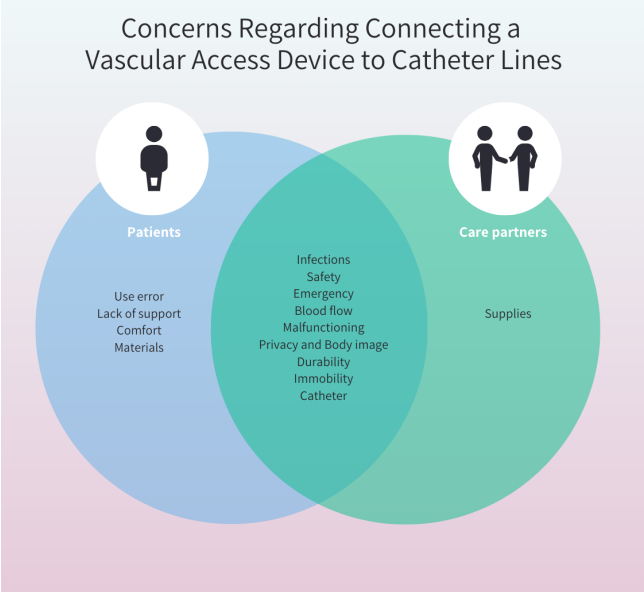

Figure 8.5: Summary of concerns wearable hemodialysis device (Secondary study population).

8.2.2 R2: What are Patients' and Care Partners' Needs and Expectations for Monitoring and Training Procedures for a Wearable Hemodialysis System?

Patients' and care partners' responses to their awareness of disease symptoms were also explored. As summarized in Table 8.2, patients and care partners notice many physical and mental changes in patients before and after they receive a hemodialysis treatment. Fluid retention, oral symptoms, fatigue, feelings, and complexion were all notable changes in patients before and after a successful hemodialysis treatment. Table 8.2 also summarizes findings from exploring patients and care partners expectations of monitoring and training procedures. In addition to learning how to operate the device, the patients and care partners expressed their interest in understanding how the device functions, specifically how the device conducts dialysis. They also expressed their desire for hands-on training that allows them to interact and use the device, particularly in different environments during different activities. Training environments and activities could be adopted using the results from section 4 and Table 8.2. Patients and care partners also long for a robust device-integrated real-time and remote monitoring system that tracks patients' health and treatment-related factors. By building a monitoring system according to users' needs, and incorporating measures for the observable disease indicators, patients and their clinical partners can better monitor patients' condition to ensure effective treatments.

Table 8.2: Summary of disease indicators before and after treatment and expectations for monitoring and training procedures for a wearable hemodialysis device
(Primary study population).

Disease indicators before treatment	Disease indicators after treatment	Expected monitoring features	Expected training procedures
Fluid retention	Fluid and weight loss	Treatment parameters	Operation
Oral symptoms	Improved oral symptoms	Follow-up care	Functions

Table 8.2 continued from previous page

Disease indicators before treatment	Disease indicators after treatment	Expected monitoring features	Expected training procedures
Fatigue	More energy	Vital signs	Error prevention and recovery
Feelings	Wellness feeling	Secondary monitoring	Emergency procedures
Complexion	Improved complexion	Safety monitoring	Blood connections
Breathing	Better breathing	Smart remote monitoring	Hands-on training
Cramping	No pain or cramping		Usage scenarios
Shaking	-		Evaluations
Itching	-		Physiology and self-care
Lack of sleep	-		
-	Physiological measurements		
-	Increased productivity		
-	Positivity		
-	Clear eyes		

8.2.3 R3: What are Clinicians' Perspectives on a Wearable Hemodialysis Device?

The goal of this research was to explore nephrologists' and nephrology nurses' perspectives of a wearable hemodialysis device to both complement previous findings from patients' and care partners' and provide additional perspectives seen from their unique clinical standpoint. Similar to the patients and care partners, the nephrologists and nephrology nurses were asked to name features that a wearable dialysis device must hold to ensure they feel confident in recommending the device to their patients. Using an inductive content analysis, the findings

show that the nephrologists and nephrology nurses share many of the same perspectives. As shown in Figure 8.6, twenty categories of ideal features were shared among both parties. Unique to the nephrology nurses included features ensuring a self-contained device that is easy to store between treatments. Additionally, the nephrology nurses highlighted ensuring features that accommodate patients' characteristics including different body shapes and patients with impaired vision.

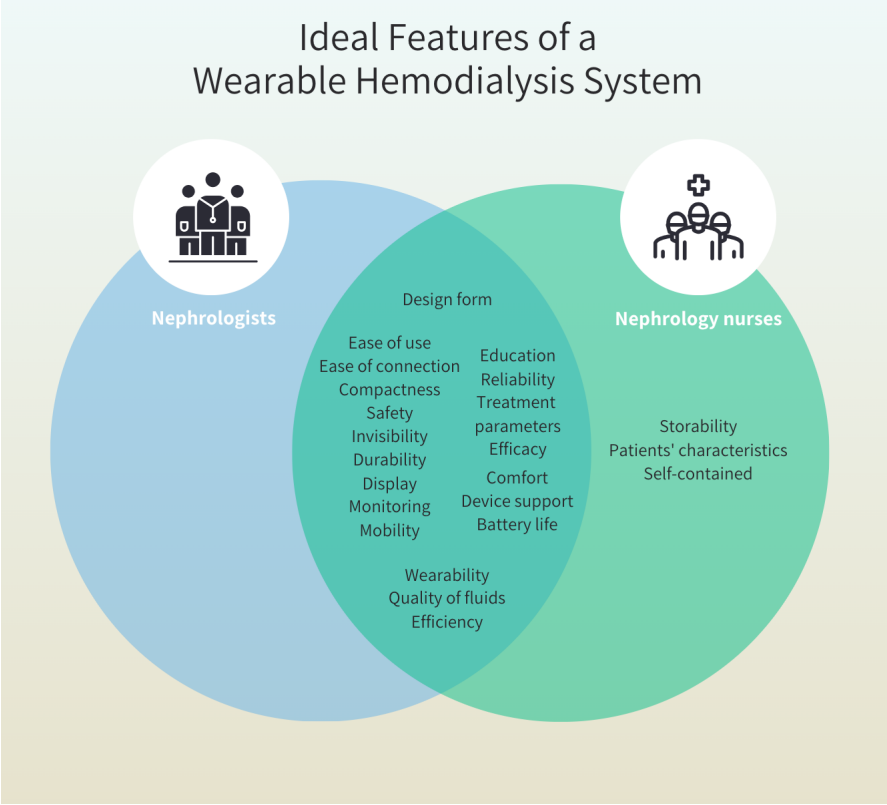

Figure 8.6: Summary of potential challenges of a wearable hemodialysis device (Clinicians study population).

The clinicians were also asked to name potential barriers to recommending a wearable hemodialysis device to patients. Similar to patients' and care partners' perspectives, many of their mentioned ideal features were also observed as barriers if not met in design. As shown in Figure 8.7, the nephrologists had unique perspectives being concerned about the visibility of the device and the risk of electric shocks associated with the device. The nephrologists also feared that the device would look scary and intimidating to patients. As a result, they feared experiencing difficulties convincing patients to consider using the device. Unique concerns among the nephrology nurses included lengthy treatment durations, the lack of patient support, and the suitability of the device for patient's living environments.

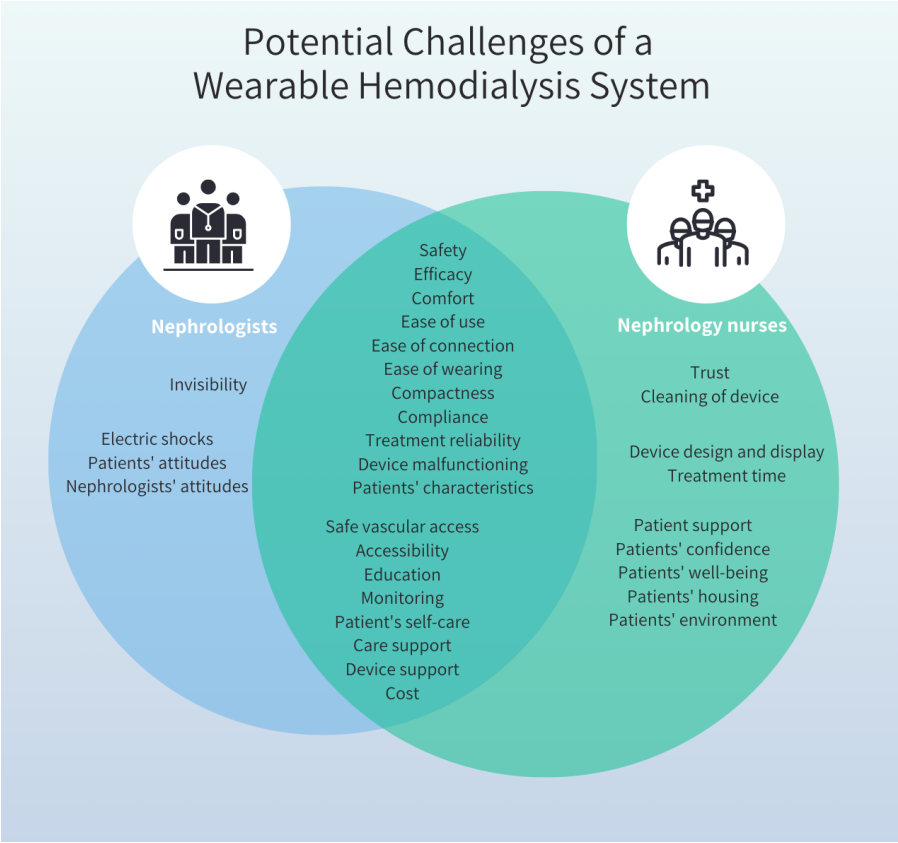

Figure 8.7: Summary of potential challenges of a wearable hemodialysis device (Clinicians study population).

Contrasting the four user groups allows for the detection of both shared and unique perspectives. As displayed in Figures 8.8 the patients, care partners, nephrologists, and nephrology nurses share many of the same perspectives in terms of the ideal features of a wearable hemodialysis device. They all long for a device that is; easy to use, easy to connect to a patient's bloodstream, safe, durable, compact, invisible, allows for unrestricted mobility, monitors the patient's treatment and health condition, and includes a simple display of vital signs, treatment parameters, and device condition. While patients and care partners focused on an ideal physical location to wear the device and the ability to select different treatment options, the clinicians highlighted ensuring good education, reliability, and efficacy. Notably, patients specifically longed for a device that does not require them to rely on assistance from a care partner.

Contrasting users' perspectives on potential challenges of a wearable hemodialysis system highlights distinct viewpoints. While, care partners and clinicians jointly expressed concerns about the lack of monitoring procedures for wearable hemodialysis treatments, patients worried about making errors while using the device. Also, while clinicians expressed concerns about ensuring safe blood access, patients feared having to frequently stick themselves with needles. Clinicians also uniquely expressed their concerns related to the accessibility and affordability of the device. They feared that insurance companies would not cover the cost of the device, rendering it unaffordable to most of their patients. Other shared and unique perspectives are displayed in Figure 8.9.

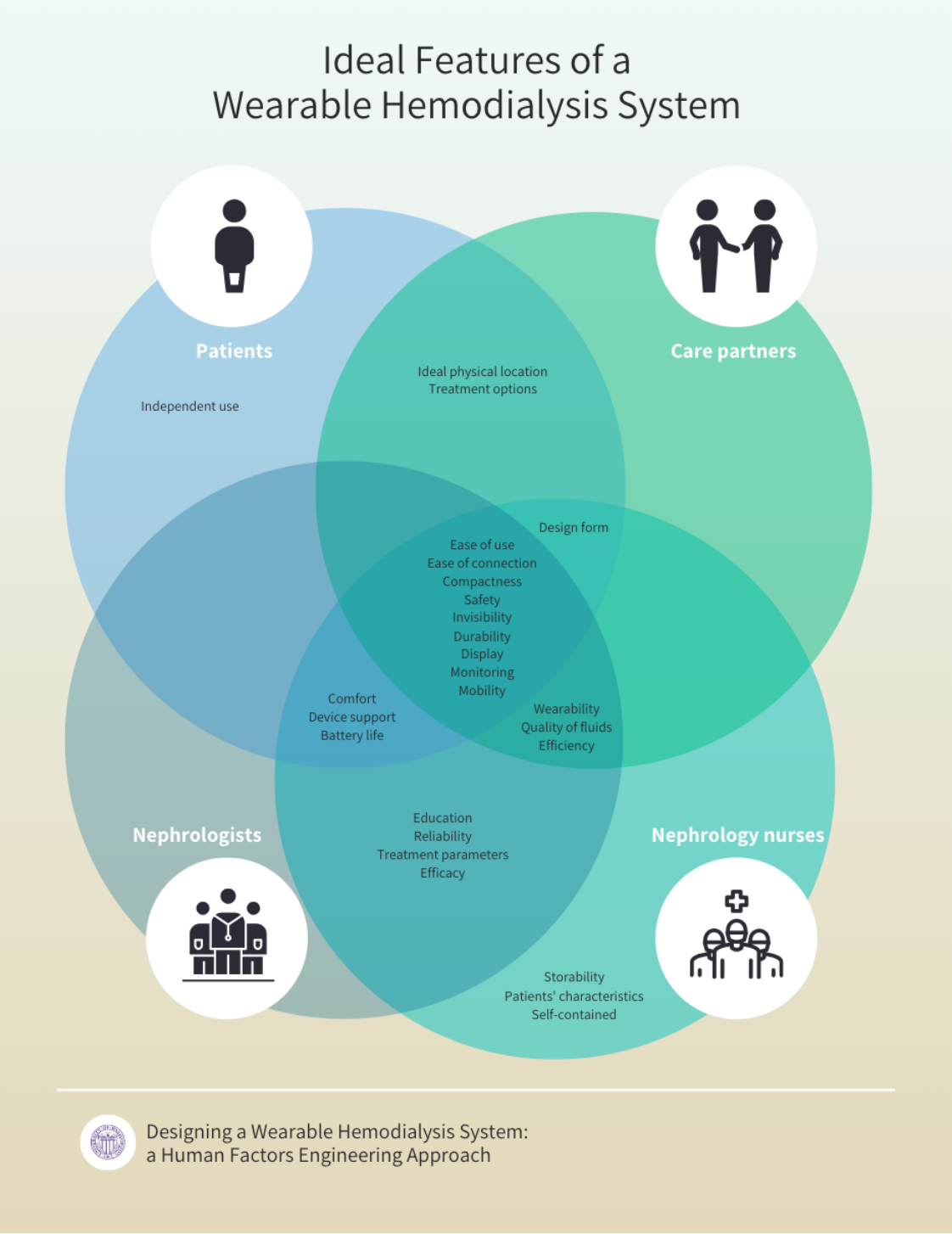

Figure 8.8: Summary Ideal Features Wearable

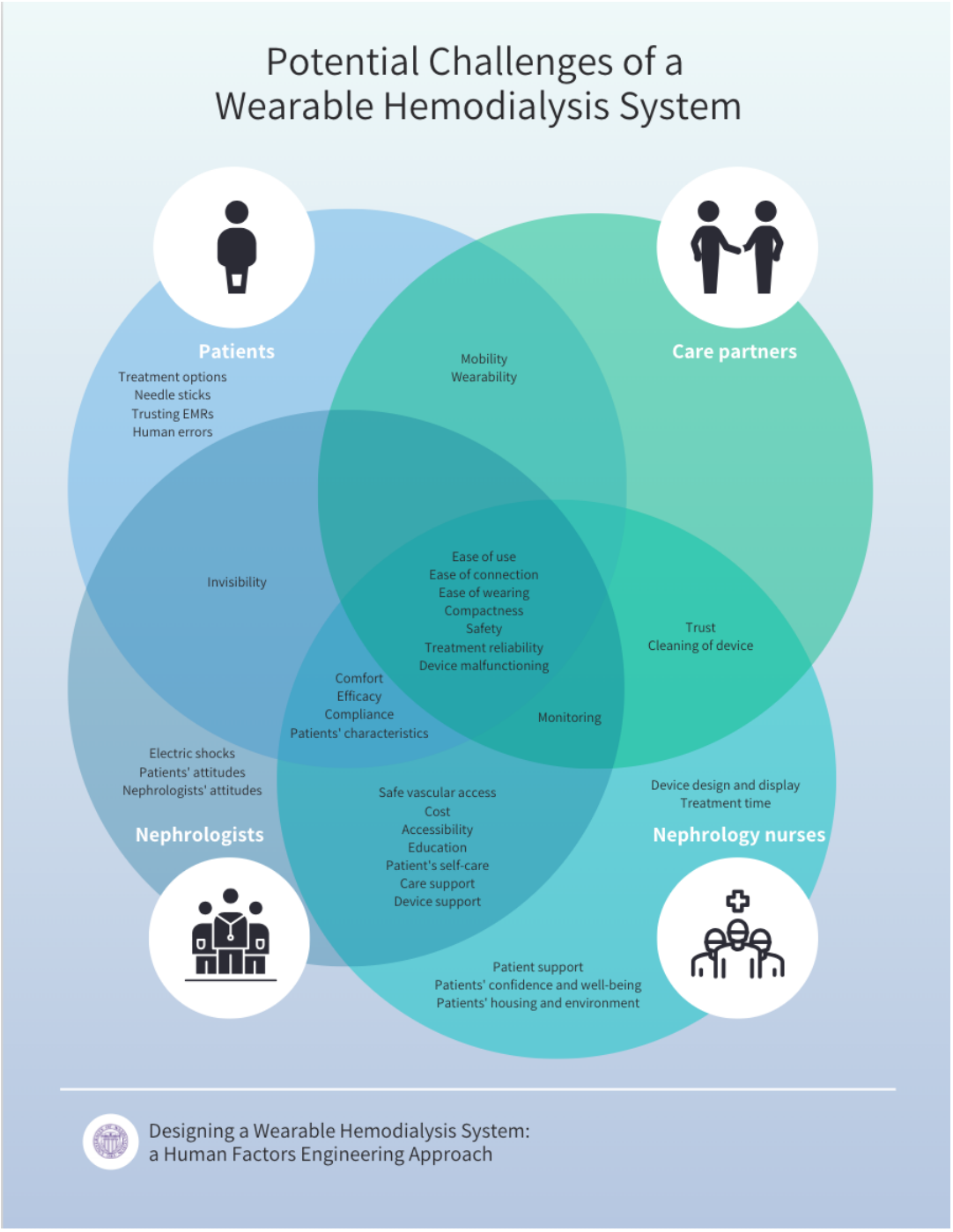

Figure 8.9: Summary Potential Challenges Wearable

8.2.4 R4: What is the Relationship among User Characteristics, Human Factors Design Principles, and Proposed Design Concepts of a Wearable Hemodialysis Device?

The goal of this study was to gain a deeper understanding of the relationship among user characteristics, human factors design principles, and proposed design concepts of a wearable hemodialysis device. First, exploratory factor analysis was adopted to gain insight into users' perception of human factors design principles for wearable medical devices (section 7.2). The findings indicated two underlying structures among seven selected principles: the principles of compactness, comfort, and invisibility loaded on one factor while the principles of safety, accuracy, and ease of connection loaded on a second factor. Considering common characteristics among variables, the first factor was labeled wearability while the second factor was labeled reliability. Interestingly, the principle of ease of use loaded on both factors indicating inefficiency in measuring a single phenomenon.

Using the knowledge from the exploratory factor analysis, the relationship between users' demographic characteristics, the human factors design principles, and five proposed design types of a wearable hemodialysis device was explored using a structural equation modeling approach (section 7.3). Modeling this relationship, the results showed that users' specific roles affect both the perceived wearability and reliability of a wearable hemodialysis device as well as preferences for a specific wearable design type. Users' age was found to affect perceived wearability and design preferences, and users' gender was found to affect design preferences only. Focusing on the human factors design principles, the results showed that both wearability and reliability affect design type preferences. Wearability was found to affects reliability and mediate the relationship between users' specific roles and design preferences as well as the relationship between users' roles and reliability.

8.3 Contributions

The results of this dissertation contribute to the fields of engineering and nephrology impacting both the current and future landscape of hemodialysis.

Impacting current hemodialysis procedures the findings from research question R1 show that patients and care partners experience both physical and mental challenges in relation

to in-center hemodialysis treatments. Addressing these challenges may relieve some of the burden patients and care partners currently experience. Additionally, the findings from research question R3 provide insight into patients' and care partners' expected training and monitoring procedures that can be used to complement current practices.

For the future landscape of wearable hemodialysis systems, the work of this dissertation presents a detailed description of users' needs highlighting the importance of incorporating users' perspectives during the early design stages. The findings from research questions R1-R3 show that users' have both shared and distinct viewpoints. Based on users' perspectives, several aspects of a wearable hemodialysis system can now be envisioned, ranging from use environments and scenarios, ideal design forms and features, and potential use challenges and barriers to adoption. Additionally, the findings from research question R4 show that users' characteristics and human factors design principles can be used to gain a deeper insight into users' preferences for particular design types. Based on findings, designers of a wearable hemodialysis system can tailor their design processes to better meet the diverse needs of users.

This dissertation has also theoretical contributions. First, this dissertation presents a methodological approach of gathering, analyzing, and contrasting users' perspectives of new wearable medical technology during the early design stages. This approach can be extended to other systems and devices whose success depends on users' acceptance. Secondly, for the human factors engineering community, this dissertation demonstrates how prominent human factors design principles can be modeled to better understand users' perspectives in design. The findings from research question R4 show that the targeted users of a wearable hemodialysis device relate design principles to different aspects of the device. The design principles of compactness, comfort, and invisibility were found to share a common underlying construct, while safety, accuracy, and ease of connection shared another different underlying construct. Most interestingly, the principle of ease of use, which was also identified as an ideal feature of a wearable hemodialysis system, shared a common underlying construct across both groups of the aforementioned principles. This realization indicates the need for a more detailed description of the term in relation to its intended measure. By incorporating a greater number of prominent human factors design principles researchers can draw more

robust conclusions regarding the underlying construct among human factors design principles. Lastly, considering the findings from this dissertation researchers in nephrology and in the field of wearable medical devices may both obtain better-targeted research areas and contrast new findings across different populations.

8.4 Limitations and Future Research

This dissertation has several limitations that guide future research directions. First and foremost, this dissertation considered a limited number of patients, care partners, nephrologists, and nephrology nurses in the United States. As a result, the findings may not be generalized across different populations and other geographical regions.

Secondly, the four research objectives considered in this dissertation were not simultaneously constructed. Rather, the objectives were realized in a sequential order during data analysis and design progression within CDI. As a result, several recruiting rounds of different user groups were conducted to gather additional perspectives. Although more diverse perspectives may be realized, this approach is both costly and time-consuming and may be confusing to the reader of this dissertation. This approach also brings other limitations as some perspectives cannot be contrasted across all participant groups.

Thirdly, although meeting patients' needs in wearable hemodialysis designs is the focus of this dissertation, this dissertation did not consider the individual needs of care partners, nephrologists, or nephrology nurses. Rather, the objective was to gather the perspectives of nephrologists, nephrology nurses, and care partners regarding the best designs considering their patients or patient-partners. Also, this dissertation did not gather perspectives form dialysis technicians, whose experiences may bring additional viewpoints.

Fourthly, this dissertation did not consider diverse demographic characteristics of intended user groups. Preferences and perspectives of the designs of a wearable hemodialysis system may depend on different body shapes or sizes **??**, patients' income in relation to affordability issues **??**, or other health conditions and disabilities that patients may have potentially impacting their viewpoints and hindering design inclusiveness. Considering these limitations, future studies should aim to recruit a greater number of participants, analyze their distinct perspectives gather their individual needs, and ensure a more diverse popula-

tion based on their demographic and geographical differences.

Lastly, while the overall goal of this dissertation is to guide the designs of a wearable hemodialysis system, no prototypes were shown to the participants. Rather, the goal was to understand users' needs and perspectives at the beginning of the design process to guide design solutions according to users' perspectives. Through an iterative human factors design process, of gathering users' needs while building and evaluating prototypes, better-targeted solutions may be obtained.

Chapter 9

SUPPLEMENTARY MATERIALS

Table 9.1: Correlations between human factors design principles.

	Distributed	Compactness	Invisibility	Safety	Accuracy	Comfort	Ease of Connection
Distributed	1.00	0.08	-0.09	0.16	0.11	-0.01	0.17
Compactness	0.08	1.00	0.44	0.28	0.25	0.46	0.24
Invisibility	-0.09	0.44	1.00	0.13	0.17	0.35	0.06
Safety	0.16	0.28	0.13	1.00	0.34	0.18	0.40
Accuracy	0.11	0.25	0.17	0.34	1.00	0.19	0.38
Comfort	-0.01	0.46	0.35	0.18	0.19	1.00	0.26
Ease of Connection	0.17	0.24	0.06	0.40	0.38	0.26	1.00

Table 9.2: Measurement model.

	Model				
	Estimate	Std.Err.	Z	p	R Square
		Factor Loadings			
Wearability					
Compactness	0.25	0.04	5.93	0.000	0.58
Invisibility	0.15	0.04	4.36	0.000	0.27
Comfort	0.16	0.04	4.49	0.000	0.38
Reliability					
Ease of connection	0.13	0.04	3.73	0.000	0.59
Safety	0.07	0.03	2.54	0.011	0.36
Accuracy	0.12	0.04	3.12	0.002	0.31
		Residual Variances			
Compactness	0.05	0.02	2.38	0.017	
Invisibility	0.06	0.01	4.83	0.000	
Comfort	0.04	0.01	3.55	0.000	
Ease of connection	0.01	0.01	2.26	0.024	
Safety	0.01	0.00	3.01	0.003	
Accuracy	0.03	0.01	2.90	0.004	
		Latent Variances			
Wearability	1.00^{+}				
Reliability	1.00^{+}				
		Latent Covariances			
Wearability w/Reliability	0.54	0.13	4.18	0.000	
		Fit Indices			
ChiSq	2.97				
CFI	1.00				
TLI	1.11				

RMSEA	0.00	
Scaled χ^2(df)	2.16(8)	0.976

$^{+}$Fixed parameter

Table 9.3: Structural equation model output for users' role.

	Model				
	Estimate	Std.Err.	Z	p	R Square
		Factor Loadings			
Wearability					
Compactness	0.93	0.14	6.68	0.000	0.60
Invisibility	1.33	0.27	4.87	0.000	0.30
Comfort	0.69	0.12	5.52	0.000	0.38
Reliability					
Safety	0.12	0.03	4.68	0.000	0.36
Accuracy	0.33	0.07	4.71	0.000	0.37
Ease of connection	0.55	0.11	4.80	0.000	0.39
		Regression Slopes			
Wearability					
Patients	1.63	0.42	3.92	0.000	
Care partners	1.70	0.51	3.36	0.001	
Nurses	0.47	0.33	1.45	0.147	
Reliability					
Patients	0.62	0.50	1.23	0.218	
Care partners	0.25	0.60	0.41	0.682	
Nurses	0.82	0.38	2.15	0.032	
Wearability	0.46	0.21	2.21	0.027	
Shoulder bag					
Patients	−2.89	0.92	−3.14	0.002	
Care partners	−1.90	1.08	−1.75	0.080	
Nurses	−0.12	0.71	−0.17	0.865	
Wearability	0.99	0.39	2.50	0.012	
Reliability	0.04	0.37	0.09	0.925	

Vest					
	Patients	−0.09	0.84	−0.11	0.912
	Care partners	1.33	0.99	1.34	0.181
	Nurses	−0.17	0.66	−0.26	0.797
	Wearability	0.83	0.37	2.27	0.023
	Reliability	−0.44	0.34	−1.30	0.194
Belt					
	Patients	−1.06	0.85	−1.25	0.212
	Care partners	−0.98	1.00	−0.98	0.329
	Nurses	−0.54	0.66	−0.82	0.412
	Wearability	0.58	0.37	1.58	0.115
	Reliability	0.25	0.34	0.72	0.474
Backpack					
	Patients	−0.17	0.79	−0.21	0.832
	Care partners	0.96	0.93	1.03	0.302
	Nurses	−0.50	0.71	−0.71	0.478
	Wearability	−0.33	0.39	−0.84	0.404
	Reliability	0.25	0.38	0.66	0.511
Distributed					
	Patients	−0.17	0.79	−0.21	0.832
	Care partners	0.96	0.93	1.03	0.302
	Nurses	−1.29	0.73	−1.77	0.077
	Wearability	−0.49	0.41	−1.19	0.234
	Reliability	0.86	0.38	2.23	0.026
			Residual Variances		
	Compactness	0.85	0.22	3.90	0.000
	Invisibility	6.10	1.02	6.01	0.000
	Comfort	1.14	0.20	5.65	0.000
	Safety	0.04	0.01	5.16	0.000

Accuracy	0.29	0.06	5.12	0.000	
Ease of connection	0.72	0.14	4.97	0.000	
Shoulder bag	5.72	0.93	6.14	0.000	
Vest	4.76	0.79	6.04	0.000	
Belt	5.21	0.81	6.47	0.000	
Backpack	6.64	1.00	6.67	0.000	
Distributed	6.50	1.07	6.06	0.000	
Patients	0.17^{+}				
Care partners	0.10^{+}				
Nurses	0.23^{+}				
		Residual Covariances			
Shoulder bag w/Vest	1.90	0.66	2.90	0.004	
Shoulder bag w/Belt	0.38	0.62	0.62	0.534	
Shoulder bag w/Backpack	2.09	0.71	2.96	0.003	
Shoulder bag w/Distributed	1.96	0.73	2.69	0.007	
Vest w/Belt	0.94	0.58	1.63	0.103	
Vest w/Backpack	2.00	0.65	3.07	0.002	
Vest w/Distributed	2.15	0.67	3.20	0.001	
Belt w/Backpack	0.52	0.63	0.81	0.416	
Belt w/Distributed	0.96	0.66	1.45	0.147	
Backpack w/Distributed	2.19	0.77	2.83	0.005	
Patients w/Care partners	-0.02^{+}				
Patients w/Nurses	-0.08^{+}				
Care partners w/Nurses	-0.04^{+}				
		Latent Variances			
Wearability	1.00^{+}				0.32
Reliability	1.00^{+}				0.34
		Constructed			
p.w.sb	1.61	0.76	2.11	0.035	

p.w.v	1.36	0.69	1.96	0.050
p.r.d	0.53	0.48	1.10	0.273
p.w.r.d	0.65	0.46	1.42	0.155
p.d.totalind	1.18	0.66	1.78	0.075
p.w.sb.total	−1.28	0.91	−1.41	0.159
cp.w.sb	1.42	0.75	1.88	0.060
cp.w.v	1.42	0.75	1.88	0.060
cp.w.r.d	0.68	0.49	1.39	0.165
n.r.d	0.70	0.45	1.55	0.120
p.w.r	0.76	0.39	1.93	0.053
cp.w.r	0.79	0.43	1.85	0.064
p.w.r.tot	1.38	0.46	2.98	0.003
w.r.d	0.40	0.26	1.53	0.127
		Fit Indices		
χ^2(df)	38.47(42)			0.627
CFI	1.00			
TLI	1.04			
RMSEA	0.00			

$^{+}$Fixed parameter

Table 9.4: Structural equation model output for users' age.

	Model				
	Estimate	Std.Err.	Z	p	R Square
		Factor Loadings			
Wearability					
Compactness	1.03	0.15	6.67	0.000	0.55
Invisibility	1.51	0.32	4.77	0.000	0.29
Comfort	0.84	0.14	5.86	0.000	0.42
Reliability					
Ease of connection	0.65	0.13	5.15	0.000	0.48
Safety	0.12	0.03	4.61	0.000	0.34
Accuracy	0.33	0.07	4.43	0.000	0.31
		Regression Slopes			
Wearability					
Age	0.03	0.01	2.45	0.014	
Reliability					
Age	−0.00	0.01	−0.16	0.873	
Wearability	0.57	0.21	2.76	0.006	
Vest					
Age	0.02	0.02	0.69	0.488	
Wearability	1.02	0.39	2.64	0.008	
Reliability	−0.49	0.33	−1.48	0.140	
Shoulder bag					
Age	−0.06	0.03	−2.09	0.036	
Wearability	0.71	0.41	1.71	0.087	
Reliability	0.08	0.37	0.22	0.823	
Backpack					
Age	−0.02	0.03	−0.77	0.439	

Wearability	−0.26	0.42	−0.63	0.528
Reliability	0.29	0.37	0.80	0.426
Distributed				
Age	0.02	0.03	0.68	0.498
Wearability	−0.41	0.44	−0.93	0.350
Reliability	0.72	0.38	1.90	0.058
Belt				
Age	0.01	0.02	0.37	0.708
Wearability	0.46	0.37	1.23	0.220
Reliability	0.23	0.33	0.68	0.498
		Residual Variances		
Compactness	0.94	0.24	3.86	0.000
Invisibility	6.18	1.06	5.85	0.000
Comfort	1.06	0.21	5.05	0.000
Ease of connection	0.61	0.15	3.95	0.000
Safety	0.04	0.01	5.17	0.000
Accuracy	0.32	0.06	5.38	0.000
Vest	4.95	0.83	5.97	0.000
Shoulder bag	6.39	0.98	6.54	0.000
Backpack	6.70	1.00	6.69	0.000
Distributed	6.93	1.09	6.36	0.000
Belt	5.28	0.80	6.61	0.000
Age	120.92 +			
		Residual Covariances		
Vest w/Shoulder bag	1.95	0.68	2.87	0.004
Vest w/Backpack	2.28	0.68	3.36	0.001
Vest w/Distributed	2.34	0.70	3.34	0.001
Vest w/Belt	0.90	0.59	1.53	0.126
Shoulder bag w/Backpack	1.93	0.73	2.66	0.008

Shoulder bag w/Distributed	1.66	0.75	2.22	0.027	
Shoulder bag w/Belt	0.67	0.63	1.06	0.291	
Backpack w/Distributed	2.39	0.79	3.04	0.002	
Backpack w/Belt	0.53	0.64	0.84	0.400	
Distributed w/Belt	0.91	0.67	1.37	0.171	
		Latent Variances			
Wearability	1.00^{+}				0.09
Reliability	1.00^{+}				0.26
		Constructed			
age.w.vest	0.03	0.02	1.81	0.071	
age.w.r	0.02	0.01	1.85	0.065	
		Fit Indices			
χ^2(df)	27.46(32)			0.696	
CFI	1.00				
TLI	1.07				
RMSEA	0.00				

$^{+}$Fixed parameter

Table 9.5: Structural equation model output for users' gender.

	Model				
	Estimate	Std.Err.	Z	p	R Square
		Factor Loadings			
Wearability					
Compactness	1.09	0.16	6.84	0.000	0.57
Invisibility	1.60	0.33	4.84	0.000	0.30
Comfort	0.86	0.15	5.77	0.000	0.41
Reliability					
Safety	0.13	0.03	4.86	0.000	0.40
Accuracy	0.33	0.07	4.50	0.000	0.33
Ease of connection	0.57	0.12	4.81	0.000	0.39
		Regression Slopes			
Wearability					
Female	0.08	0.25	0.34	0.735	
Reliability					
Female	0.42	0.30	1.42	0.155	
Wearability	0.61	0.21	2.87	0.004	
Shoulder bag					
Female	1.54	0.55	2.82	0.005	
Wearability	0.67	0.41	1.62	0.106	
Reliability	−0.17	0.37	−0.46	0.649	
Vest					
Female	0.42	0.52	0.81	0.417	
Wearability	1.17	0.40	2.92	0.004	
Reliability	−0.54	0.34	−1.58	0.114	
Belt					
Female	−0.61	0.50	−1.21	0.228	

Wearability	0.49	0.38	1.30	0.192
Reliability	0.26	0.34	0.76	0.447
Backpack				
Female	−0.16	0.57	−0.28	0.779
Wearability	−0.29	0.43	−0.67	0.501
Reliability	0.21	0.38	0.56	0.578
Distributed				
Female	−0.70	0.59	−1.18	0.236
Wearability	−0.40	0.45	−0.90	0.368
Reliability	0.78	0.39	2.01	0.045
		Residual Variances		
Compactness	0.91	0.25	3.66	0.000
Invisibility	6.12	1.06	5.80	0.000
Comfort	1.09	0.21	5.11	0.000
Safety	0.04	0.01	4.74	0.000
Accuracy	0.31	0.06	5.31	0.000
Ease of connection	0.71	0.15	4.83	0.000
Shoulder bag	6.17	0.94	6.56	0.000
Vest	4.92	0.85	5.81	0.000
Belt	5.22	0.79	6.59	0.000
Backpack	6.80	1.01	6.71	0.000
Distributed	6.84	1.09	6.27	0.000
Female	0.25^{+}			
		Residual Covariances		
Shoulder bag w/Vest	1.65	0.67	2.47	0.013
Shoulder bag w/Belt	0.87	0.62	1.40	0.160
Shoulder bag w/Backpack	2.13	0.72	2.96	0.003
Shoulder bag w/Distributed	1.88	0.74	2.55	0.011
Vest w/Belt	0.97	0.59	1.64	0.101

Vest w/Backpack	2.20	0.69	3.22	0.001	
Vest w/Distributed	2.45	0.71	3.46	0.001	
Belt w/Backpack	0.51	0.64	0.80	0.423	
Belt w/Distributed	0.84	0.66	1.27	0.204	
Backpack w/Distributed	2.40	0.79	3.03	0.002	
		Latent Variances			
Wearability	1.00^{+}				0.00
Reliability	1.00^{+}				0.30
		Constructed			
w.r.d	0.47	0.29	1.63	0.103	
		Fit Indices			
χ^2(df)	33.67(32)			0.387	
CFI	0.99				
TLI	0.98				
RMSEA	0.02				

$^{+}$Fixed parameter

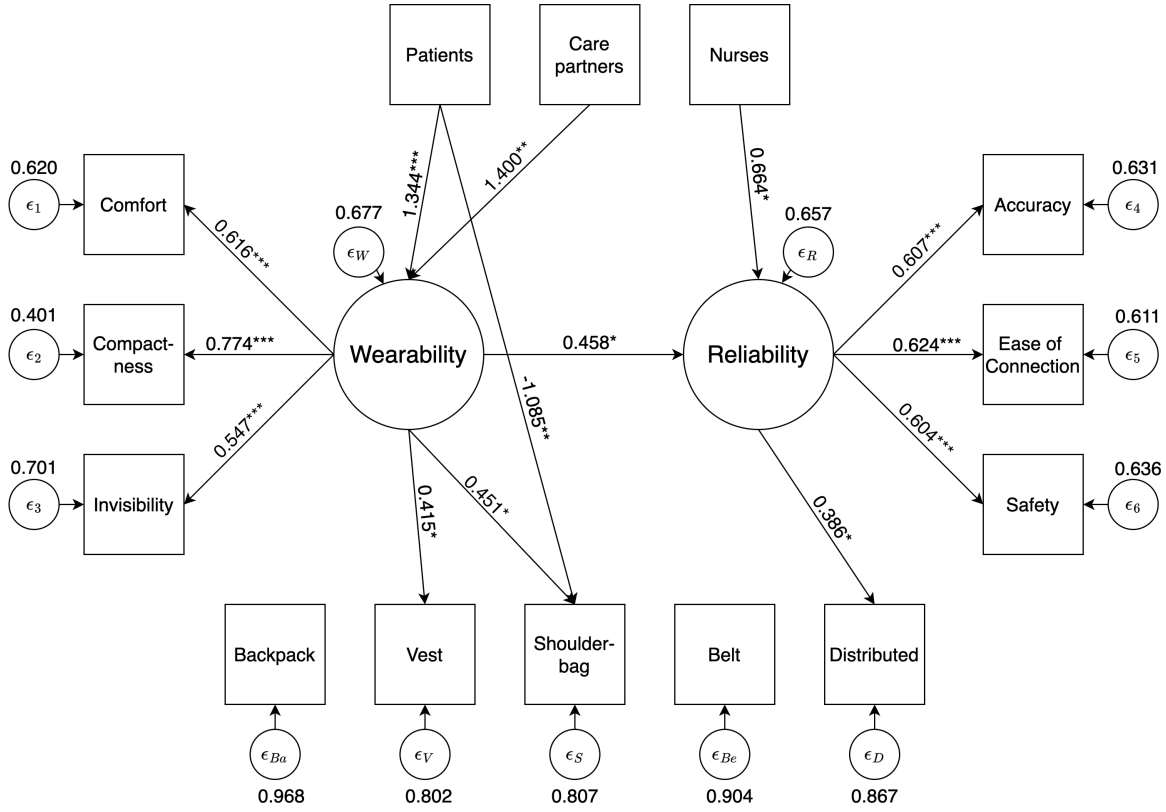

Figure 9.1: Structural equation model examining the relationship between user role, human factors design principles, and proposed design types of a wearable hemodialysis device. The coefficients displayed are the partially standardized estimates. Correlations between design types are omitted for ease of viewing. Nephrologists are the baseline comparison for user roles.

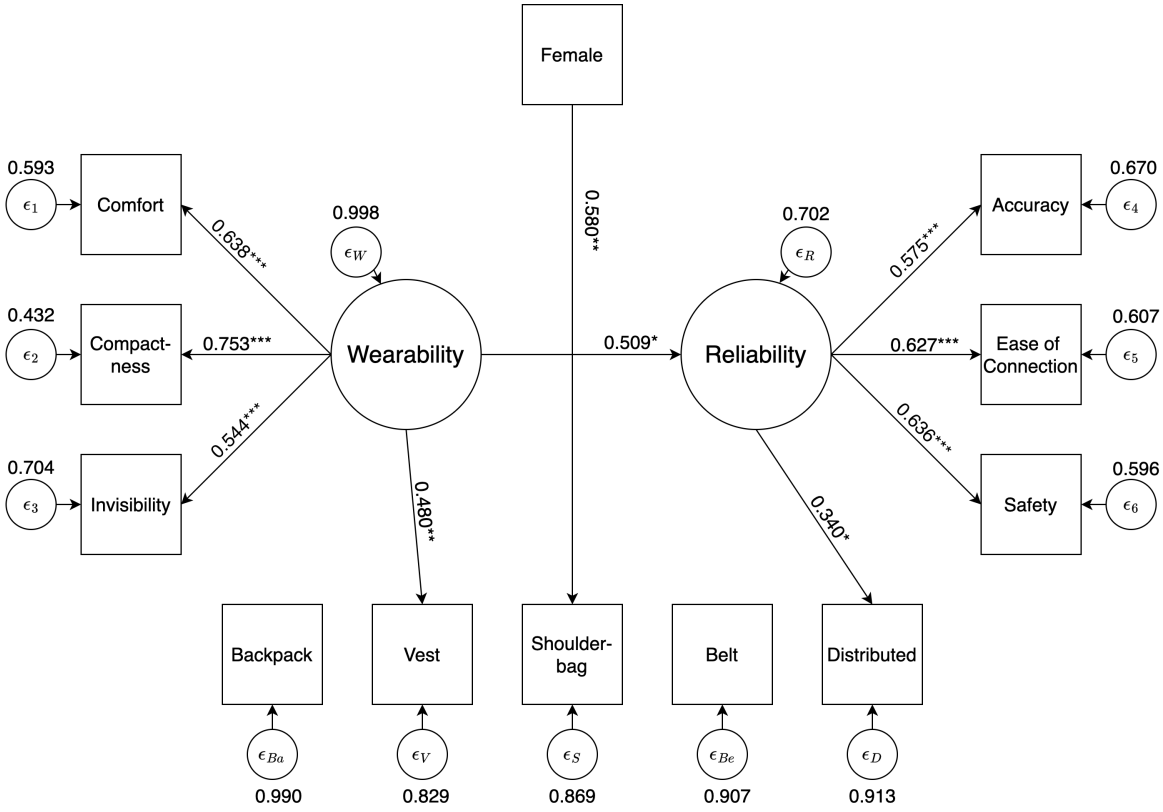

Figure 9.2: Structural equation model examining the relationship between user gender, human factors design principles, and proposed design types of a wearable hemodialysis device. The coefficients displayed are the partially standardized estimates. Correlations between design types are omitted for ease of viewing. Males are the baseline comparison group.

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VITA

[J]:Peer-reviewed journal articles

[C]:Peer-reviewed conference proceedings

[P]:Conference presentations

[J1] Jónsdóttir, A.A., Kessler, L., & Kim, J-E. (Under revision). Nephrologists' Perspectives for the Designs of Mobile Dialysis Devices: A Human Factors Engineering Approach.

[J2] Jónsdóttir, A. A., Lazo, G. R., Kessler, L., Colobong Smith, N., & Kim, J-E.(2022). Nephrology Nurses' Perspectives for the Designs of Mobile Hemodialysis Devices: A Human Factors Engineering Approach. Nephrology Nursing Journal, 49(6), 481-530.

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[P2] Jónsdóttir, A. A., Firestone, S., Kessler, L., & Kim, J-E. "Patients’ and Care Partners’ Perspectives in Designing a Vascular Connection Device for a Portable Hemodialysis Device," IISE Annual Conference, Seattle, WA (2022 May).

[P3] Jónsdóttir, A. A., Kessler, L., & Kim, J-E. "Establishing Successful Mobile Dialysis Experiences: Users’ Needs for Training Programs and Monitoring systems," IEA 2021.

[P4] Jónsdóttir, A. A., Kessler, L., Rim., S Y., & Kim, J-E. “Users’ Needs in Designing a Mobile Dialysis Device: Insights from an Interview in a Mixed Methods Study,” HFES Annual Meeting (2020 October).

[P5] Jónsdóttir, A. A., Kim, J-E., Kang, Z., & Mandal, S., “The Effects of Language Use and Time Pressure on Eye Movement in Online Education,” IISE Annual Conference, Orlando, FL (2019).